IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

HEALTH CHOICE GROUP, LLC and	§	
JAIME GREEN, on Behalf of the	§	
United States of America, et al.	§	
	§	
v.	§	**Case No. 5:17-CV-126-RWS-CMC**
	§	
BAYER CORPORATION, et al.	§	

REPORT AND RECOMMENDATION
OF THE UNITED STATES MAGISTRATE JUDGE

The above-referenced cause of action was referred to the undersigned United States Magistrate Judge for pretrial purposes in accordance with 28 U.S.C. § 636. The following motion is before the Court:

> **Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint (Docket Entry # 38).**

A hearing was held in Texarkana on May 14, 2018. After hearing the arguments of counsel, reviewing the 100-page First Amended Complaint, and reviewing the relevant pleadings, presentation materials, other papers, and case law, the Court recommends the motion to dismiss be **GRANTED IN PART and DENIED IN PART**. Specifically, the Court recommends

- Defendants' motion to dismiss Jaime Green's claims be granted and Jaime Green be dismissed as a co-relator in this action;
- Defendants' motion to dismiss under Rule 12(b)(6) be denied; and
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- Defendants' motion to dismiss under Rule 9(b) be granted to the extent Relators' federal and state law FCA claims be dismissed without prejudice and Relator Health Choice Group be allowed to replead. Relator Health Choice Group shall have until twenty days following any Order Adopting this Report and Recommendation to replead its claims, to the extent it deems appropriate to address the deficiencies identified herein.

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I. BACKGROUND

This is a False Claims Act ("FCA") *qui tam* action originally filed on June 19, 2017 by Health Choice Group, LLC ("Health Choice Group") against Bayer Corporation ("Bayer"), Amgen, Inc. ("Amgen"), Onyx Pharmaceuticals, Inc. ("Onyx"), AmerisourceBergen Corporation ("Amerisource"), and Lash Group ("Lash") (collectively "Defendants"). In October 2017, the United States of America ("United States") and all thirty-one states named as plaintiffs ("Plaintiff States") declined to intervene after an investigation of the allegations.[1] Health Choice Group's original complaint was unsealed and served.

On January 12, 2018, the United States and the Plaintiff States (collectively the "Government"), by and through their *qui tam* Relators – Health Choice Group and newly-added relator Jaime Green (collectively "Relators") – filed the First Amended Complaint ("FAC").[2] The FAC raises substantially the same allegations as the original complaint. Specifically, the FAC alleges Defendants have engaged in three schemes that violate the Anti-Kickback Statute ("AKS") and, thus, the FCA.

Bayer, Amgen, and Onyx are pharmaceutical or biopharmaceutical companies. Relators allege these defendants caused the submission of false claims for reimbursement for three prescription medications (collectively the "Covered Products") to government healthcare programs.

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[1] Plaintiff States are Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.

[2] Relator Green is a nurse based out of Houston, Texas. (FAC, ¶ 27). From approximately November 2015 through April 2017, Green worked as a nurse educator for Adempas, a Bayer product. *Id*. Green performed her work pursuant to a contract between Bayer and Green's then-employer, Ashfield Healthcare LLC ("Ashfield"). *Id.*

Of the three medicines at issue in this case, two are Bayer products: Betaseron (used to treat multiple sclerosis) and Adempas (used to treat pulmonary hypertension). (FAC, ¶ 2). The third medicine, Nexavar (used to treat cancer), has been co-marketed by Bayer, Amgen, and Onyx. *Id.* Relators claim Amerisource and Lash carried out certain drug product support programs for Betaseron and Nexavar.

Relators seek relief against Defendants for violations of the FCA, 31 U.S.C. § 3729(1)(1)(A) - (C). Relators claim Defendants: (i) knowingly presented or caused to be presented to the United States false or fraudulent claims for payment (Count 1, FAC, ¶¶ 205-09); (ii) knowingly made, used, and caused to be made and used false records and statements to get false or fraudulent claims paid or approved by the United States (Count 2, FAC, ¶¶ 210-15); and (iii) knowingly conspired to violate 31 U.S.C. §§ 3729(a)(1)(A) and (B) and to defraud the United States by causing the Medicare and Medicaid Programs to pay for false claims (Count 3, FAC, ¶¶ 216-20). Relator's remaining claims for relief rely upon the state False Claims Act statutes in the Plaintiff States (Counts 4-34, FAC, ¶¶ 221-375).

Relators allege claims for reimbursement for the three medicines were false under the federal FCA and similar state laws based on three alleged schemes—referred to as the free nurse services, white coat marketing by nurse educators, and reimbursement support services schemes—which violated the AKS. According to Relators, Bayer and Amgen's kickback schemes encompass every Prescriber that, since at least 2006, received, directly or indirectly, free nurse or support services that were paid for by Bayer or Amgen or that received a nurse educator that purported to provide "education" on behalf of Bayer and Amgen. (FAC, ¶¶ 184-86). Relators allege Bayer and Amgen and their co-Defendants profited from the illegal schemes, and Medicare, Medicaid, TRICARE, and Veteran Administration Healthcare were made to bear the costs. *Id*. ¶ 187.

The FAC lists fifteen confidential Prescribers as some examples of prescribers who received the free nurse education services or support services offered by Defendants in part to induce a recommendation of the Covered Products. The FAC also contains information from seven Confidential Interviewees ("CIs") and Relator Green. As one example, Relators allege as follows:

> Prescriber 1, a doctor located in Golden Valley, Minnesota. Prescriber 1 was among the 1,000 highest prescribers of Betaseron to Medicare patients in 2014 and 2015. Prescriber 1 had patients educated by the nurse educators and utilized the support services provided by Defendants. CI-2 was first introduced to Prescriber 1 in 2007. CI-2 educated Betaseron patients until 2015, including patients of Prescriber 1.

Id. ¶ 189.

II. DEFENDANTS' MOTION TO DISMISS

Defendants move to dismiss Relators' FAC pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). Pursuant to Rule 12(b)(6), Defendants assert Relators do not, and cannot, satisfy the elements of falsity, scienter, or causation, so Counts 1 and 2 should be dismissed with prejudice. Defendants further argue Relators fail to plead their claims of fraud with particularity as required by Rule 9(b) so all of Relators' FCA claims (Counts 1-3) should be dismissed.]Finally, according to Defendants, the FAC asserts claims beyond the statute of limitations period and improperly attempts to add a new relator (Jaime Green) in violation of the FCA's first-to-file rule.[3]

III. LEGAL STANDARDS

A. Rule 12(b)(1)

Under FED. R. CIV. P. 12(b)(1), "a claim is properly dismissed for lack of subject-matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the claim." *In re FEMA Trailer Formaldehyde Prods. Liab. Litig*., 668 F.3d 281, 286 (5th Cir. 2012) (internal

[3] Although Defendants' motion raises the first-to-file rule under Rule 12(b)(6), the Court considers the first-to-file rule a jurisdictional bar and thus considers it under Rule 12(b)(1).

quotation marks omitted). In ruling on a Rule 12(b)(1) motion to dismiss, the court may rely on (1) the complaint alone, presuming the allegations to be true, (2) the complaint supplemented by undisputed facts, or (3) the complaint supplemented by undisputed facts and by the court's resolution of disputed facts. *Den Norske Stats Oljeselskap As v. HeereMac Vof,* 241 F.3d 420, 424 (5th Cir. 2001). The burden of establishing subject matter jurisdiction is on the party seeking to invoke it. *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001).

When challenging subject matter jurisdiction under Rule 12(b)(1), a party can make a facial attack or a factual attack. *See Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. May 1981). In a facial challenge, the movant attacks jurisdiction based only on the allegations in the complaint. *Anselmo v. United States*, No. CV 17-00043-BAJ-RLB, 2018 WL 1006450, at *2 (M.D. La. Jan. 30, 2018) (citing *Lee v. Verizon Commc'ns, Inc.*, 837 F.3d 523, 533 (5th Cir. 2016)). For purposes of the motion, the allegations in the complaint are taken as true. *Id.* "If a defendant has posed a facial challenge to the complaint, the court considers the allegations in the complaint and documents that are judicially noticed." *United States ex rel. Acad. Health Ctr., Inc. v. Hyperion Found., Inc*., No. 3:10-CV-552-CWR-LRA, 2014 WL 3385189, at *40 (S.D. Miss. July 9, 2014), *report and recommendation adopted sub nom. United States ex rel. Acad. Health Ctr., Inc. v. Hyperion Found*., Inc., No. 310CV00552CWRLRA, 2017 WL 3260134 (S.D. Miss. July 31, 2017).

"Conversely, a challenge is factual if the defendant submits affidavits, testimony, or other evidentiary materials." *Anselmo*, 2018 WL 1006450, at *2 . The court need not accept the plaintiff's allegations as true in a factual challenge, and the court is "free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Id.* (quoting *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981)).

B. Rule 12(b)(6)

Rule 12(b)(6) of the Federal Rules of Civil Procedure authorizes the dismissal of a case for failure to state a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6). The court must accept as true all well-pleaded facts contained in the plaintiff's complaint and view them in the light most favorable to the plaintiff. *Baker v. Putnal,* 75 F.3d 190, 196 (5th Cir. 1996). In deciding a Rule 12(b)(6) motion, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Gonzalez v. Kay,* 577 F.3d 600, 603 (5th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007)).

To "survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Gonzalez,* 577 F.3d at 603 (quoting *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "It follows, that 'where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—'that the pleader is entitled to relief.'" *Id.*

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend under Rule 15(a) before dismissing with prejudice. *United States ex rel. Bennett v. Medtronic, Inc*., 747 F. Supp. 2d 745, 761 (S.D. Tex. 2010) (citing *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.,* 313 F.3d 305, 329 (5th Cir. 2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."); *see also United States ex rel. Adrian*

v. Regents of the Univ. of Cal., 363 F.3d 398, 403 (5th Cir. 2004) ("Leave to amend should be freely given, and outright refusal to grant leave to amend without a justification . . . is considered an abuse of discretion." (internal citation omitted))). However, a plaintiff should be denied leave to amend a complaint if the court determines the proposed change clearly is frivolous or advances a claim or defense that is legally insufficient on its face. *See Ayers v. Johnson,* 247 Fed. Appx. 534, 535 (5th Cir. 2007) (unpublished) (per curiam) ("'[A] district court acts within its discretion when dismissing a motion to amend that is frivolous or futile.'") (quoting *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.,* 195 F.3d 765, 771 (5th Cir.1999)).

C. Rule 9(b)

Claims brought under the FCA must comply with Rule 9(b), which requires pleading with particularity in cases alleging fraud. Rule 9(b) provides that in order to state a claim for fraud the plaintiff must state with particularity the circumstances constituting the fraud. *See* FED. R. CIV. P. 9(b). However, malice, intent, knowledge, and other conditions of a person's mind may be alleged generally. *Id.*

Rule 9(b) relaxes the requirement for conditions of the mind such as scienter. *United States ex rel. Vavra v. Kellogg Brown & Root, Inc.,* 903 F. Supp. 2d 473, 485 (E.D. Tex.2011), *rev'd on other grounds,* 727 F.3d 343 (5th Cir. 2013) "Although Rule 9(b) expressly allows scienter to be 'averred generally,' simple allegations that defendants possess fraudulent intent will not satisfy Rule 9(b)." *Id.* (citing *Dorsey v. Portfolio Equities, Inc.,* 540 F.3d 333, 339 (5th Cir. 2008) (quoting *Melder v. Morris,* 27 F.3d 1097, 1102 (5th Cir. 1994))). "The plaintiffs must set forth *specific facts* supporting an inference of fraud." *Id.* (emphasis in original).

Under Fifth Circuit precedent, a dismissal for failure to plead fraud with particularity is treated as a dismissal for failure to state a claim upon which relief can be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Vavra,* 903 F. Supp. 2d at 485 (citing *Shandong Yinguang Chem. Indus. Joint Stock Co., Ltd. v. Potter,* 607 F.3d 1029, 1032 (5th Cir. 2010); *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.,* 565 F.3d 200, 206 (5th Cir. 2009); *Motient Corp. v. Dondero,* 529 F.3d 532, 535 (5th Cir. 2008); *Southland Secs. Corp. v. INSpire Ins. Solutions, Inc.,* 365 F.3d 353, 361 (5th Cir. 2004)).

IV. APPLICABLE LAW

A. FCA background

"The False Claims Act . . . imposes liability on any person who knowingly presents . . . a false or fraudulent claim for payment or approval, to an officer or employee of the United States." *Kellogg Brown & Root Servs., Inc. v. United States, ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015) (internal quotations and citations omitted). A person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or "(C) conspires to commit a violation of [A or B]," violates the FCA and is subject to civil liability. 31 U.S.C. § 3729(a)(1)(A)–(C). Claims under § 3729(a)(1)(A) are commonly referred to as "presentment claims." *Capshaw v. White*, No. 3:12-CV-4457-N, 2017 WL 3841611, at *7 (N.D. Tex. Jan. 23, 2017), *reconsideration denied sub nom. United States ex rel. Capshaw v. White*, No. 3:12-CV-4457-N, 2017 WL 3841612 (N.D. Tex. June 13, 2017) (citing *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 511 (N.D. Tex. 2012)). Claims under § 3729(a)(1)(B) are commonly referred to as "false statement claims." *Id.*

"The FCA may be enforced not just through litigation brought by the Government itself, but also through civil *qui tam* actions that are filed by private parties, called relators, 'in the name of the Government.'" *Id.* (quoting 31 U.S.C. § 3730(b)). The claims in this case are predicated on the AKS, 42 U.S.C. § 1320a-7b(b), "compliance with which is a condition of payment for any claim submitted to a federal health care program, including Medicaid." *United States ex rel. Banigan v. PharMerica, Inc.*, No. CV 07-12153-RWZ, 2018 WL 2012684, at *1 (D. Mass. Apr. 30, 2018) (citation omitted).

In a *qui tam* suit under the FCA, the relator files a complaint under seal and serves the United States with a copy of the complaint and a disclosure of all material evidence. 31 U.S.C. § 3730(b)(2). "After reviewing these materials, the United States may 'proceed with the action, in which case the action shall be conducted by the Government,' or it may 'notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.'" *Carter*, 135 S. Ct. at 1973 (quoting 31 U.S.C. § 3730(b)(4)). Regardless of the option the United States selects, "it retains the right at any time to dismiss the action entirely, § 3730(c)(2)(A), or to settle the case, § 3730(c)(2)(B)." *Carter*, 135 S. Ct. at 1973-74.

"To encourage relators to bring suits on the government's behalf, Congress gave them a stake in the controversy: they can share up to 30 percent of any proceeds ultimately recovered." *United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 926 (D.C. Cir. 2017) (citing 31 U.S.C. § 3730(d)). If the government elects to intervene in, and assume control of, any *qui tam* action, the relator's share of the recovery becomes capped at 25 percent. 31 U.S.C. § 3730(b)(2), (d)(1). A relator who brings a meritorious *qui tam* action receives attorney's fees and court costs in addition to a percentage of

recovered proceeds. *See State Farm Fire and Cas. Co. v. United States ex rel. Rigsby*,137 S.Ct. 436, 440 (2016).

"Over time, Congress learned that the bounty available to *qui tam* relators created 'the danger of parasitic exploitation of the public coffers.'" *Shea*, 863 F.3d at 926 (quoting *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994)). To curtail abusive suits, Congress established "a number of restrictions" on *qui tam* actions, including the first-to-file bar. *Rigsby*,137 S.Ct. at 440.

Under the FCA "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). When a "later-filed complaint alleges the same material or essential elements of fraud described in a pending *qui tam* action, § 3730(b)(5)'s jurisdictional bar applies." *United States ex rel. Branch Consultants v. Allstate Ins. Co.* ("*Branch II*"), 560 F.3d 371, 378 (5th Cir. 2009)."The focus is on whether an investigation into the first claim would uncover the same fraudulent activity alleged in the second claim." *United States v. Planned Parenthood of Houston*, 570 Fed.Appx. 386, 389 (5th Cir. 2014). The first-to-file bar is a relatively broad bar to later-filed actions. *Id.*

A relator cannot avoid the first-to-file bar "by simply adding factual details or geographic locations to the essential or material elements of a fraud claim against the same defendant described in a prior compliant." *Branch II*, 560 F.3d at 378. This is because "a relator who merely adds details to a previously exposed fraud does not help reduce fraud or return funds to the federal fisc, because once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *Id.* (internal quotations and citation omitted).

B. The Anti–Kickback Statute

The AKS, in relevant part, provides that

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any time or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a–7b(b)(2).

The FAC alleges three separate theories of AKS violations. The first and third schemes (free nurse and reimbursement support services) allege the services provided by both support programs are illegal remuneration provided to induce *physicians* to prescribe or recommend the Covered Products. (FAC, ¶¶ 89, 91-107; 146-73). The second scheme (white coat marketing by nurse educators) alleges the salaries paid to nurse educators are illegal remuneration to induce those *nurses* to recommend the Covered Products. *Id*. ¶¶ 90, 108-45.

C. Elements of an FCA claim

The test for FCA civil liability is: (1) "whether 'there was a false or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due.'" *United States ex rel. Longhi v. Lithium Power Techs., Inc.,* 575 F.3d 458, 467 (5th Cir. 2009), *cert. denied,* 559 U.S. 1067 (2010) (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370, 376 (4th Cir. 2008)).

"To state a claim under the FCA, subsection (a)(1), a relator must allege that the defendant 'knowingly' made a 'false or fraudulent claim' to the United States Government." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.,* 355 F.3d 370, 376 (5th Cir.2004) (quoting 31 U.S.C. § 3729(a)(1)). "To state a claim under subsection (a)(2), the relator must allege the defendant 'knowingly' made or used a 'false record or statement to get a false or fraudulent claim' paid by the government." *Id.* (quoting 31 U.S.C. § 3729(a)(2)).

Mindful of these considerations, the Court now examines the substance of Defendants' motion to dismiss, starting with Defendants' argument that the FAC improperly added Relator Green in violation of the FCA's first-to-file bar.

V. WHETHER RELATOR GREEN IS BARRED FROM INTERVENING IN THIS CASE ON FIRST-TO-FILE GROUNDS

A. Defendants' assertions

Defendants argue Health Choice Group's original complaint in this case bars intervention by Relator Jaime Green, who was added in the FAC, because the first-to-file rule prohibits intervention in an earlier-filed action based on the same allegations already pled. According to Defendants, "comparing the two Relators' allegations in the FAC against Health Choice's allegations in the original complaint shows that the FAC contains virtually verbatim recitations of the alleged 'schemes' from the original complaint. *Compare* FAC ¶¶ 92-173, *with* Original Complaint ¶¶ 76-152." (Docket Entry # 38 at pg. 36). Defendants state 78 of the 82 paragraphs containing these allegations in the FAC were already made in the original complaint.[4]

[4] Defendants assert Relators made only inconsequential changes to a handful of the other 78, pre-existing paragraphs. *See*, *e.g.*, FAC, ¶ 93 (adding single sentence of Green's salary with

Relators argue the first-to-file rule only applies when new actions are initiated if the new action arises out of the same allegations as those disclosed in a prior and pending action. According to Relators, the first-to-file rule does not apply in this case, where the relator simply filed an amended complaint with an additional relator. According to Relators, Green is not an "opportunistic successive plaintiff," as in the cases cited by Defendants. (Docket Entry # 52 at pg. 39). Rather, Green was one of the confidential interviewees, quoted in the original complaint, who worked with Health Choice Group to initiate this action.

B. Applicable law

The first-to-file bar provides that "[w]hen a person brings an action under this subsection, *no person other than the Government may intervene* or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). Some courts have limited the first-to-file bar's applicability only to a later separate action or intervention under FED. R. CIV. P. 24 based on textual analysis of § 3730(b)(5). *See United States ex rel. Precision Co. v. Koch Indus., Inc*., 31 F.3d 1015, 1018 (10th Cir.1994) ("*Precision II*") (allowing an original relator, a corporation, to join two corporate stockholders as relators pursuant to Rule 15 amendment because their joinder did not constitute impermissible intervention in violation of the first-to-file rule); *see also United States v. Educ. Mgmt. Corp.,* 871 F. Supp. 2d 433, 459 (W.D. Pa.2012) (declining to dismiss amendment to add relator because "[t]he plain text of § 3730(b)(5) does not apply to the unique procedural status of this case because [the new relator] is not 'intervening' or bringing a

Ashfield); *id*. at ¶¶ 108, 110 (adding nonparty "Ashfield"); *id*. at ¶ 116 (changing "Relator" to "HCG"); *id*. at ¶ 167 (changing "the Covered Products" to "Betaseron or Nexavar").

'related action'"); *United States ex rel. Howard v. Lockheed Martin Corp.,* No. 99–285, 2011 WL 4348104, at *4 (S.D. Ohio Sept.16, 2011) (following *Precision II's* interpretation).

"Some courts have simply applied the § 3730(b)(5) bar to consolidated or amended complaints without providing any analysis of the provision's text." *United States ex rel. Boise v. Cephalon, Inc.*, Civil Action No. 08-287, 2014 WL 5089671, at *3 (E.D. Penn. Oct. 9, 2014) (citing *United States ex rel. Nowak v. Medtronic, Inc.,* 806 F. Supp. 2d 310, 334 (D. Mass. 2011) (applying the first-to-file bar to relators joined through a consolidated complaint); *Palladino ex rel. U.S. v. VNA of S. N.J., Inc.,* 68 F. Supp. 2d 455, 477 (D.N.J.1999) (applying the first-to-file bar to a relator added by amended complaint)). "Other courts have more directly disputed [*Precision II's*] interpretation of § 3730(b)(5)." *Boise*, 2014 WL 5089671, at *3.

For example, in *United States ex rel. Fry v. Guidant Corp.,* No. 03–0842, 2006 WL 1102397 (M.D. Tenn. Apr. 25, 2006), the court applied the first-to-file rule to bar the addition of a second relator to plaintiff's proposed second amended complaint, concluding the Tenth Circuit erred in *Precision II* because it carved out an "exception" to the first-to-file rule and the Fourth and Ninth Circuits have held the first-to-file rule is exception-free. *See id.* at *5–6 (citing *United Staes ex rel. LaCorte v. Wagner,* 185 F.3d 188, 191 (4th Cir. 1999) and *United States ex rel. Lujan v. Hughes Aircraft Co.,* 243 F.3d 1181, 1187 (9th Cir. 2001)); *see also United States ex. rel. Denenea v. Allstate Ins. Co.*, 2011 WL 231780, at *3 (E.D. La. 2011) (noting "a relator could not 'circumvent the first-to-file doctrine by seeking entrance to the action via amended complaint'").

The court in *Capshaw* rejected the relators' attempt to circumvent the first-to-file jurisdictional bar "by arguing the addition of Whatley [a putative relator] via amendment [did] not qualify as an 'intervention' within the meaning of Section 3730(b)(5)." 2017 WL 3841611, at *5.

To support this argument, the relators in *Capshaw* relied on an Eastern District of Texas opinion, relied upon by Relators in this case, that adopted the narrow definition of intervention used by the Tenth Circuit in *Precision II*. *Id.* (citing *United States v. Homeward Residential, Inc*., No. 4:12-CV-461, 2015 WL 3776478, at *4 (E.D. Tex. June 17, 2015)).

In *Homeward*, the court found persuasive the reasoning of the Tenth Circuit regarding the term "intervene" within § 3730(b)(5). 2015 WL 3776478, at *4 (citing *Precision II*, 31 F.3d 1015, 1017 (10th Cir.1994) (stating § 3730(b)(5) "implies intervention of the types set forth in Rule 24(b)(2), and the addition of parties does not constitute intervention")). In *Capshaw*, the court did not need to decide whether to adopt this reasoning, noting the court in *Homeward* rejected the first-to-file jurisdictional bar because the relator "made new allegations within the amended complaint." 2017 WL 3841611, at *5 (quoting *Homeward*, 2015 WL 3776478, at *4). As explained by the court in *Capshaw*:

> In fact, the *Homeward* court based its decision to reject the reasoning of several other courts, which held the first-to-file jurisdictional bar applied to adding relators via amendment, on the fact that those relators did not assert new allegations or claims. *Id.* That is not the case here. As discussed below, here, the new relators do not add additional allegations that satisfy the 'essential facts' or 'material elements' standard. Nor do the new allegations result in new causes of action against the Defendants. Accordingly, *Homeward* does not apply in this case.

Capshaw, 2017 WL 3841611, at *5. The court concluded Whatley's allegations only added detail to the previously alleged fraud allegations, and her claims were barred by the first-to-file rule. *Id*. The court dismissed Whatley as a co-relator in the action. *Id*. at *6.

C. Discussion

Although not cited by the parties, the Supreme Court has defined the contours of party intervention in the FCA context:

> A 'party' to litigation is '[o]ne by or against whom a lawsuit is brought.' Black's Law Dictionary 1154 (8th ed.2004). An individual may also become a 'party' to a lawsuit by intervening in the action. *See id.,* at 840 (defining 'intervention' as '[t]he legal procedure by which . . . a third party is allowed to become a party to the litigation'). As the Court long ago explained, '[w]hen the term [to intervene] is used in reference to legal proceedings, it covers the right of one to interpose in, *or become a party to,* a proceeding already instituted.' *Rocca v. Thompson,* 223 U.S. 317, 330, 32 S.Ct. 207, 56 L.Ed. 453 (1912) (emphasis added). The Court has further indicated that intervention is the requisite method for a nonparty to become a party to a lawsuit. *See Marino v. Ortiz,* 484 U.S. 301, 304, 108 S.Ct. 586, 98 L.Ed.2d 629 (1988) (*per curiam*) (holding that 'when [a] nonparty has an interest that is affected by the trial court's judgment . . . the better practice is for such a nonparty *to seek intervention* for purposes of appeal' because 'only parties to a lawsuit, or those that properly become parties, may appeal an adverse judgment' (internal quotation marks omitted; emphasis added)).

United States ex rel. Eisenstein v. City of New York, New York, 556 U.S. 928, 933 (2009). The Supreme Court further held a nonparty can become a party to litigation only through intervention even where the nonparty is a real party in interest under Rule 17. *Id.* at 935.

Recently, a district court applied this "broad and comprehensive definition of intervention" and rejected a relator's request for the court to follow the Tenth Circuit's holding in *Precision II*. *See In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.* (*No. II*), No. CV 11-6476 (FLW), 2018 WL 2427126, at *13 (D.N.J. May 30, 2018). A review of the facts of *Plavix* helps place the relator's argument in context.

"JKJ filed the Original *qui tam* Complaint, identifying its partners anonymously as 'Partner A,' 'Partner B,' and 'Partner C.'" *Id*. at *1. At some point between the filing of the original

complaint and the filing of the second amended complaint, Partner B left the JKJ partnership, and Dr. Gurbel joined the JKJ partnership to replace Partner B. *Id.* at *2. The defendants later moved to dismiss, arguing JKJ's continuation as the plaintiff after the substitution of Dr. Gurbel for Partner B was prohibited by the first-to-file bar. The defendants argued any curative amendment to add JKJ's members as relators was also prohibited by the first-to-file bar. *Id.*

The court first determined "the original JKJ had no separate legal existence from its members, Partners A, B, and C." *Id.* at *11. Thus, there was not a separate JKJ legal entity that could persist as the nominal plaintiff when Partner B left the partnership and Dr. Gurbel joined into the new JKJ partnership. *Id.* Relying on the Supreme Court's definition of "intervention," the court held the new JKJ partnership, as a nonparty to the original complaint and having not yet come into existence, could not, under the FCA's first-to-file bar, intervene in the action by being joined as a relator in the second amended complaint. *Id.* at *13.

The court then considered JKJ's request that "it be allowed to file a Third Amended Complaint to name its individual members, as well as JKJ, as the plaintiff relators." *Id.* JKJ argued such amendment should be permitted as a permissive amendment under Rule 15 or as an amendment to substitute a real party in interest under Rule 17. *Id*. According to the court, the first-to-file bar, on its face, would appear to preclude such amendment. *Id*. (citing 31 U.S.C. § 3730(b)(5) ("no person other than the Government may intervene"); *Eisenstein*, 556 U.S. at 933 ("intervention is the requisite method for a nonparty to become a party to a lawsuit.")).

JKJ asked the court to follow the holding of *Precision II*, wherein the Tenth Circuit "narrowed the application of the first-to-file bar only to Rule 24 intervention, and found the joinder of parties through a Rule 15(a) amendment [was] permitted under the FCA." *Plavix*, 2018 WL

2427126, at *13 (citing *Precision II*, 31 F.3d at1017–18 ("when § 3730(b)(5) speaks of intervention, it means to prohibit parties unrelated to the original plaintiff from joining the suit to assert a claim based on the same facts relied upon by the original plaintiff")). The court in *Plavix* first noted the holding in *Precision II* is "in clear tension with the Supreme Court's decision in *Eisenstein*." *Plavix*, 2018 WL 2427126, at *14.

The *Plavix* court then noted the Tenth Circuit had recently revisited its *Precision II* holding in *United States ex rel. Little v. Triumph Gear Sys., Inc*., 870 F.3d 1242 (10th Cir. 2017), *cert. denied sub nom. United States ex rel. Little v. Triumph Gear Sys., Inc*., 138 S.Ct. 1298 (2018). *Plavix*, 2018 WL 2427126, at *14. "There, the court observed that *Precision II* was likely no longer good law, in the wake of the intervening Supreme Court precedent in *Eisenstein*, but nevertheless managed an elaborate savings construction to find that *Precision II* need not be directly overruled in the particular factual circumstances presented." *Id*. (citing *Triumph Gear*, 870 F.3d at 1247 ("But we aren't writing on a blank slate; our analysis must account for this court's decision in *Precision*, 31 F.3d 1015."). As pointed out by the court in *Plavix*, in discussing the continued precedential effect of *Precision II*, the Tenth Circuit stated as follows:

> In the FCA context, the Supreme Court has defined 'intervention' as 'the requisite method for a nonparty to become a party to a lawsuit.' . . . Under that broad formulation, intervention takes place when a non-party becomes a party—regardless of the mechanism by which that occurs. . . . Rigidly applying that definition here would make for an easy resolution. Before the amended complaint was filed, Little and Motaghed weren't parties. After its filing, they were. Thus, under *Eisenstein's* definition, they intervened—and the first-to-file rule would bar their claims.

Plavix, 2018 WL 2427126, at *14 (citing *Triumph Gear*, 870 F.3d at 1247).

According to the *Plavix* court, the Tenth Circuit "salvaged *Precision II* by noting that, unlike the joined parties in *Precision II*, the new plaintiffs in *Triumph Gear* entered the action by some means other than a Rule 15 amendment." *Plavix*, 2018 WL 2427126, at *14 (citing *Triumph Gear*, 870 F.3d at 1248). The Tenth Circuit also pointed out the new relators in *Precision II* were the sole stockholders of a corporate entity, and the existing plaintiff had added the new relators.[5] *Triumph Gear*, 870 F.3d at 1247-48. Thus, *Precision II* was not controlling in *Triumph Gear.*

The court in *Plavix* agreed with the Tenth Circuit's own interpretation that *Precision II* on its face is inconsistent with *Eisenstein* but declined to follow the Tenth Circuit's attempted reconciliation of *Precision II* to the "Supreme Court's clear pronouncement on intervention." *Plavix*, 2018 WL 2427126, at *14. The court noted *Precision II* was never the law in the Third Circuit, and in light of its conflict with the governing law, found it to be neither binding nor persuasive authority. *Id.* Similarly here, the Court finds *Precision II* to be neither binding nor persuasive authority.

At the filing of the original complaint in this action, the only party plaintiff was Health Choice Group. The joinder of Jaime Green "through any procedural device at this juncture would constitute a party intervention under *Eisenstein*." *Plavix*, 2018 WL 2427126, at *14. Because the FCA's first-to-file bar unambiguously bars all such intervention, it applies in this case to prevent any further amendment to add Green as a relator. *Id*.

The Court further notes Green would be barred by the first-to-file rule for the same reasons explained by the court in *Capshaw*. Like the situation in *Capshaw*, the factual allegations asserted by co-relator Green only add detail to the previously alleged fraud allegations asserted by Health

[5] In *Triumph Gear*, Blyn filed the original complaint, and the amended complaint was filed by Little and Motaghed with no mention of Blyn. *Triumph Gear*, 870 F.3d at 1245.

Choice Group in the original complaint. While Green's allegations add details, they allege the same essential elements and facts of the allegedly fraudulent schemes. *See Capshaw*, 2017 WL 3841611, at *5. The FAC does not allege any new causes of action as a result of the additional information provided by Green. *Id.* at *6.

As discussed above, a relator cannot circumvent the first-to-file bar merely by pleading additional details of an alleged fraud already disclosed in an earlier-filed complaint. *Branch* II, 560 F.3d at 378. The additional details added in the FAC do nothing to put the Government on notice of new conduct, let alone any fraud. The Court therefore recommends Jaime Green be dismissed as a co-relator in this action.

VI. RULE 12(b)(6) MOTION TO DISMISS COUNTS 1-2

A. Relators' allegations

1. Generally

In Count 1, Relators allege Defendants presented false claims for payment in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A). (FAC, ¶¶ 205-09). In Count 2, Relators allege Defendants used false statements in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B). *Id.* ¶¶ 210-15.

2. The three alleged schemes

a. Free nurse services

In the first scheme (free nurse services), Bayer and Amgen offered free nurse education and patient management services to induce Prescribers to recommend Bayer and Amgen products over those made by competitors. *Id.* ¶ 92. Bayer and Amgen provided these services through Amerisource nurses. *Id.*

Seeking to exploit the need of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe Bayer and Amgen products. *Id.* ¶ 94. The free nurse services became a powerful tool in the hands of Bayer and Amgen sales people: in exchange for prescribing Bayer and Amgen products, Prescribers reduced the time and cost required to treat those patients, freed up time to see other patients, and increased profitability. *Id.* ¶¶ 96-107.

b. White coat marketing by nurse educators

In the second scheme (white coat marketing by nurse educators), Bayer and Amgen paid nurse educators to act as undercover sales agents. *Id.* ¶ 108. Because Prescribers are oftentimes skeptical of drug reps, Bayer and Amgen relied heavily on teams of nurses supplied by Amerisource to promote Bayer and Amgen products. *Id.* ¶ 110. Bayer and Amgen contrived a "disease awareness" program and deployed nurse educators to influence Prescribers and their staff to recommend Bayer and Amgen products. *Id.* ¶ 115. In truth, however, these nurse educators were nothing more than "white-coated" sales reps: (1) they had received sales training from Bayer and Amgen; (2) they were actively used by Bayer and Amgen to drive sales; (3) they gained access to Prescribers to drive prescriptions; (4) they were expressly tasked to promote Bayer and Amgen products; and (5) they also engaged in direct marketing to patients on behalf of Bayer and Amgen. *Id.* ¶¶ 116-145.

c. Reimbursement support services

In the third scheme (reimbursement support services), with assistance from Amerisource, Bayer and Amgen offered Prescribers free reimbursement support services in exchange for prescribing Bayer and Amgen products. *Id.* ¶ 146. When a Prescriber receives payment from

Medicare or Medicaid programs for so-called "evaluation and management services" (a technical term for an office visit), the payment is intended to compensate the Prescriber for medical care given, as well as various administrative tasks associated with the patient's care. *Id.* ¶¶ 152-53. These administrative tasks include various reimbursement support services such as, among other things, conducting a patient's prescription drug insurance benefit verification, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, managing the process that results in obtaining prior authorizations, and managing the resulting paper trail (collectively "Support Services" or "reimbursement support services"). *Id.* ¶ 153. The costs associated with Support Services are significant, and under Federal and state law, they must be borne solely by Prescribers. *Id.* ¶ 153.

The FAC alleges that, to induce Prescribers to prescribe Bayer and Amgen products, Bayer and Amgen sales reps offered Prescribers a reimbursement support team to manage the administrative tasks associated with prescribing the drug. *Id.* ¶ 157. Support Services were only made available to Prescribers if they prescribed Bayer and Amgen products. *Id.* ¶ 167.

3. The theories of AKS violations

The FAC alleges the free nurse services and those provided by the reimbursement assistance program reduced the operating expenses of doctors who otherwise may have borne the expense of providing such services to their patients and/or the doctors' staff. *Id*. ¶¶ 89, 91. Relators contend those services constituted illegal AKS remuneration unlawfully intended to induce doctors to prescribe the Covered Products. *Id*. ¶¶ 89, 91-107, 146-73. Regarding the second scheme, the FAC alleges the salaries paid to nurse educators are unlawful remuneration to induce those nurses to recommend the Covered Products. *Id*. ¶¶ 90, 108-11. The FAC alleges generally the nurse educators

did not merely "educate" others about the products at issue, but also affirmatively "recommended" those products to patients, doctors, and their staff, which the FAC calls "white coat marketing." *Id*. ¶¶ 140, 145. The FAC asserts the AKS prohibits Defendants "from paying non-employees to 'recommend'" the Covered Products to others. *Id*. ¶ 114.

B. Applicable law

Under § 3729(a)(1)(A), Relators must allege: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (*i.e.*, that involved a claim)." *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 259 (5th Cir. 2014) (quotations and citations omitted). Section 3729(a)(1)(B) creates liability for one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." An underlying false claim is an element of both sections. *Rigsby*, 794 F.3d 457, 476–77 (5th Cir. 2015), *aff'd* 137 S. Ct. 436 (2016) ("To prove a violation of both § 3729(a)(1) and § 3729(a)(1)(B), the [relators] had to show that the claim presented for payment . . . was false.").

The elements of an AKS violation Relators must plead under 42 U.S.C. § 1320a-7b(b)(2) are that Defendants: (1) offered or paid remuneration to others; (2) to induce them to purchase, order, or recommend purchasing any good or item that may be paid by a federal health care program, and (3) did so knowingly and willfully. *See United States v. Shoemaker*, 746 F.3d 614, 627 (5th Cir. 2014).

C. Defendants' assertions

Defendants assert Relators do not, and cannot, satisfy the elements of falsity, scienter, or causation, so Counts 1 and 2 should be dismissed with prejudice. Specifically regarding their motion

to dismiss for failure to state a claim upon which relief may be granted, Defendants argue the following.

First, according to Defendants, the FAC fails to establish any "false" claim because it fails to allege facts to plausibly show Defendants violated the AKS. Defendants asserts two of Relators' theories (free nurse and reimbursement support services) do not state a kickback violation because they explicitly allege that only product-specific support was provided for the three medicines at issue, and guidance materials from the Office of the Inspector General of the U.S. Department of Health and Human Services have made clear that such product-specific support services that do not provide substantial independent value to doctors are not illegal remuneration under the AKS.

Defendants assert Relators' other theory (white coat marketing by nurse educators) also fails to state an AKS violation because those nurses merely educated doctors and patients about the Covered Products, rather than "recommending" the medicines because of any alleged remuneration. Defendants argue this theory also fails because it relies on a faulty legal premise that all promotional activities by non-employee health care providers necessarily violate the AKS.

Second, even if Relators had alleged Defendants violated the AKS and thereby created "false" claims, Defendants contend the FAC falls short of alleging Defendants *knowingly* did so. Thus, according to Defendants, Relators have failed to allege facts that establish the requisite scienter.

Third, Defendants assert Relators have not alleged facts to show Defendants' actions caused the submission of a false claim to a government healthcare program. According to Defendants, at most, Relators claim the alleged acts occurred over a period of several years and speculate the acts

must have caused the submission of a claim to a government healthcare program during that time. According to Defendants, such "conjecture" fails to establish causation.

D. Discussion

1. Whether Counts 1 and 2 should be dismissed because the FAC fails to plead the essential element of falsity

a. Whether the free nurse services theory and the reimbursement support services theory allege unlawful remuneration to physicians in violation of the AKS

Defendants' assertions

Defendants assert Relators' allegations do not, and cannot, establish falsity because they do not plausibly allege any violation of the AKS. According to Defendants, Relators' central premise that free nurse and reimbursement support services provide illegal remuneration under the AKS is "incorrect as a matter of law because each of the services described are limited to the support of one of the [Covered Products] and provide no substantial, independent value to prescribers." (Docket Entry # 38 at pg. 9). Recognizing the FAC devotes several pages to discussing the law and the OIG guidance that allegedly demonstrate these services are unlawful remuneration to doctors in violation of the AKS, *see, e.g.* FAC ¶¶ 7, 107, Defendants argue the FAC fails to mention any of the OIG guidance specific to the types of product support programs at issue here. Defendants argue the omitted OIG guidance provides that product support programs such as these are not unlawful remuneration to doctors because those services are provided solely in connection with the medicines and do not provide substantial independent value to doctors.

What constitutes remuneration

The AKS states in relevant part that it is illegal to "knowingly and willfully solicit[ ] or receive[ ] any remuneration (including any kickback, bribe, or rebate) . . .

> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a–7b.

Recognizing "the language of that section is generally very broad," *Feldstein v. Nash Cmty. Health Servs., Inc.*, 51 F. Supp. 2d 673, 681 (E.D. N.C. 1999),"Congress authorized the Office of the Inspector General of the United States Department of Health and Human Services ('OIG') to issue advisory opinions and promulgate regulatory safe harbors under the AKS." *MedPricer.com, Inc. v. Becton, Dixon & Co.*, 240 F. Supp. 3d 263, 269 (D. Conn. 2017), *adhered to on reconsideration*, No. 3:13-CV-1545 (MPS), 2017 WL 1234102 (D. Conn. Apr. 3, 2017) (citing 42 U.S.C. § 1320a–7d). While not binding, the OIG has offered further guidance on the meaning of "remuneration." For example, the OIG indicated in its Program Guidance for Ambulance Suppliers that the term "remuneration" means "virtually anything of value" including goods, meals, and gifts. *Jones-McNamara v. Holzer Health Sys.*, 630 Fed. Appx. 394, 400 (6th Cir. 2015) (quoting OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14252 (Mar. 24, 2003)).

Several courts have affirmed this expansive understanding of remuneration. Remuneration can include anything of value—and in any form—which is given in return for, or to induce, a referral for federal healthcare services:

> The text [of the statute] refers to 'any remuneration.' That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended. 'Remunerates' is defined as 'to pay an equivalent for service.' Webster Third New International Dictionary (1966). By including such

> items as kickbacks and bribes, the statute expands 'remuneration' to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

United States ex rel. Bartlett v. Ashcroft, 39 F. Supp. 3d 656, 677–78 (W.D. Pa. 2014) (quoting *United States v. Greber,* 760 F.2d 68, 71 (3d Cir.1985)).

In the Compliance Program Guidance for Pharmaceutical Manufacturers issued by the OIG on May 5, 2003 ("2003 OIG Guidance"), the OIG highlighted several known areas of potential risk. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731-01, 2003 WL 2010428, at *23734 (May 5, 2003). "The discussion highlights potential risks under the anti-kickback statute arising from pharmaceutical manufacturers' relationships with three groups: purchasers (including those using formularies) and their agents; persons and entities in a position to make or influence referrals (including physicians and other health care professionals); and sales agents." *Id*. at *23735. Under "Relationships with Purchasers and their Agents," "Product Support Services" was one area of potential risk discussed:

> Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Id.

Under "Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals," the OIG noted "[p]harmaceutical manufacturers and their agents may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' products, even though the persons or entities may not themselves purchase (or in the case of GPOs or PBMs, arrange for the purchase of) those products." *Id.* at *23737. According to the OIG, these remunerative relationships potentially implicate the AKS. The OIG's discussion focuses on relationships with physicians, "but the same principles would apply when evaluating relationships with other parties in a position to influence referrals, including, without limitation, pharmacists and other health care professionals." *Id.* The OIG advised as follows:

> Any time a pharmaceutical manufacturer provides *anything of value* to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business).

Id. at *23737 (emphasis added).

Whether there is a distinction between "purchasers" and "prescribing physicians"

Defendants argue long-standing OIG guidance provides that support services provided by a pharmaceutical manufacturer do not implicate the AKS if they are tied to support of the purchased product and offer no substantial independent value. In response, Relators argue Defendants

incorrectly apply OIG guidance requiring a showing of "other substantial independent value to the purchaser" because this case involves "prescribing physicians" instead of "purchasers." According to Relators, the section of the 2003 OIG Guidance regarding "Relationships with Purchasers and their Agents," which states services that have no substantial independent value to the purchaser may not implicate the AKS, does not apply to "prescribing physicians."

Rather, according to Relators, the OIG has made clear in the 2003 OIG Guidance – under "Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals" – that unlawful remuneration is involved where, as here, a prescriber receives any "service" that would "eliminate an expense the physician would have otherwise incurred" or any "service" is "sold to a physician at less than fair market value." (Docket Entry # 52 at pgs. 7-8) (quoting 68 FR 23731-01, 2003 WL 2010428, at IIB(2)(b)(B)(1)(b)). Relators contend the services in question satisfy both of these tests because the free nurse and reimbursement support services eliminate staff and administrative expenses a Prescriber would have to incur each time it writes a prescription, and Bayer and Amgen do not charge the Prescribers fair market value for the benefits they receive under these programs. And even if the OIG's Guidance for "purchasers" does apply, Relators assert the FAC adequately pleads AKS violations because the free nurse and reimbursement support services provide substantial value to the Prescribers that extend beyond product support; this is so because both programs eliminate substantial expenses the Prescribers would otherwise have to incur.

In their reply, Defendants assert Relators' artificial distinction between "purchasers" and "prescribing physicians" ignore the OIG's other statements on this issue, which were expressly directed to services to physicians and took the same approach contained in the 2003 OIG Guidance.

For example, the OIG issued an advisory opinion in 2000, three years before the OIG Guidance was issued, addressing free assistance given by "[d]rug manufacturers . . . to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products." Advisory Opinion No. 00-10, 2000 WL 35747420, at *4 (Dec. 15, 2000). According to the OIG, because "these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. Therefore, standing alone, these services have no substantial independent value and do not implicate the Federal anti-kickback statute." *Id.*

However, the OIG also cautioned the AKS may be implicated "when drug manufacturers combine these types of reimbursement support services with other services or programs which do confer an independent financial benefit upon referring providers." *Id*. at *5. As one example, the OIG explained that "coupling a reimbursement support service with a program either requiring payment for ordered products only if the referring provider is paid or guaranteeing a minimum 'spread' between the purchase price and third party reimbursement levels would implicate the anti-kickback statute." *Id.* According to the OIG, such programs eliminate the normal financial risks facing providers, "potentially raising the risk of overutilization and increased Federal health care program costs."[6] *Id.*

[6] In its advisory opinion, the OIG found the program at issue fell into the latter category and implicated the AKS because it coupled "reimbursement support services with extended payment terms and, if necessary, an invoice credit or replacement vial of the Drug." Advisory Opinion No. 00-10, 2000 WL 35747420, at *5. "These additional elements confer[red] an independent financial benefit upon referring physicians by shifting the financial risk of unanticipated delays and denials associated with obtaining third party payor reimbursement from the prescribing physicians to the Company." *Id.*

Defendants further assert courts have consistently applied the same 2003 OIG Guidance to services provided to physicians. Defendants cite two cases in support of this assertion: (1) *United States ex rel. Wood v. Allergan, Inc*., 246 F. Supp. 3d 772, 807 (S.D.N.Y. 2017), *motion to certify appeal granted*, No. 10-CV-5645 (JMF), 2017 WL 1843288 (S.D.N.Y. May 4, 2017) (analyzing OIG Guidance's language in context of benefits given to physicians and noting defendant's argument "is not without some force given the language of the . . . Office of Inspector General's Guidelines"); and (2) *United States ex rel. Forney v. Medtronic, Inc*., No CV 15-6264, 2017 WL 2653568 (E.D. Pa. June 19, 2017) (relying on the part of the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers regarding "Relationships with Purchasers and their Agents," wherein the OIG indicates product support services that are specifically tied to the support of the purchased product," standing alone, do not implicate the AKS; rather, such services may constitute illegal remuneration if those services provide some "substantial independent value to the purchaser.").[7]

Relators have not presented, nor has the Court's own research found, a case that has expressly applied the distinction advocated by Relators here. Moreover, as pointed out by Defendants, the 2003 OIG Guidance discusses both physicians and purchasers throughout, expressly

[7] Although Defendants rely on the *Forney* case for both their Rule 12(b)(6) and Rule 9(b) arguments (see Docket Entry # 38 at pgs. 10 & 12, n.1), the Court discusses the *Forney* case in its discussion below on Rule 9(b). Notably, the court in *Forney* held the relator failed to allege with the particularity Rule 9(b) requires that the free services saved the providers money. 2017 WL 2653568, at *4. "For example, [the relator] ha[d] not specified which of the services that Medtronic provided in exchange for purchasing Medtronic products would not have had to have been otherwise performed by the physician or the physician's staff. All that [the relator had] alleged with particularity about the free services themselves is that Medtronic provided technical product support in connection with the purchase of its products." *Id.* The court noted that if the relator filed a second amended complaint, "she must describe with sufficient specificity how Medtronic's free services crossed the line separating permissible product support from illegal remuneration with independent value to the purchaser" and also "demonstrate that any independent value to the purchaser was *substantial*." *Id*. (emphasis in original).

referencing providers with respect to "Product Support Services" under "Relationships with Purchasers and their Agents." (Docket Entry # 66 at pg. 3) (citing 2003 WL 2010428, at *23735 ("[I]f a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a *referring provider* (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns.") (emphasis added)).

The Court finds the distinction between purchasers and prescribers made by Relators is an unnecessary one. In the Court's view, one can show independent value by showing the goods or services provided by the manufacturer eliminated an expense the physicians would have otherwise incurred. Relators indicate as much in their reply wherein they argue the services at issue provide independent value to the Prescribers beyond product support because the services eliminate substantial expenses the Prescribers would otherwise have to incur. (Docket Entry # 75 at pg. 3). A 2012 OIG advisory opinion and statements of the court in the *Wood* case, cited by Defendants as support for their assertion that courts consistently apply the same OIG Guidance to services provided to physicians, further illustrate this.

In the 2012 advisory opinion, the OIG addressed a hospital's proposal to provide free access to an electronic interface to community physicians that would allow those physicians to transmit orders for certain services to, and receive the results of those services from, the hospital. No. 12-20, 2012 WL 7148096, at *1 (Dec. 12, 2012). In determining whether the proposed arrangement would constitute remuneration to the participating physicians under the AKS, the OIG first reiterated that *any arrangements which relieve physicians of financial obligations they would otherwise incur* pose significant risk. *Id*. at *2 (emphasis added). The OIG then pointed out its distinction between free

items and services that are integrally related to the offering of a provider's or supplier's services, and those that are not. *Id.* For instance, the OIG stated "a free computer provided to a physician by a laboratory would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement."[8] *Id*. (citing 56 Fed. Reg. 35952, 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations)).

In *Wood*, the relator did not allege Allergan provided free services to support use of a prescribed drug. Rather, the relator alleged Allergan violated the AKS by providing "valuable remuneration to physicians, including a no-cost suite of products and office supplies consisting of large shipments of Allergan drugs, supplies of cataract surgery patient care kits, physician-branded practice-related medical instructions for physicians to provide to patients, and pre-printed physician prescription pads." 246 F. Supp. 3d at 806. Allergan argued the supplies were of "nominal" value and benefitted patients rather than physicians, thus "removing them from the realm of remuneration." *Id.* Regarding the patient instruction sheets and pre-printed prescription pads, Allergan argued the instruction sheets lacked any marketing utility as they were provided to patients after their surgeries and the prescription pads could only be used to prescribe Allergan drugs, eliminating any independent value to physicians. *Id.* at 808.

[8] The OIG concluded the proposed arrangement would not, under the particular facts, implicate the AKS because interface access would be integrally related to the Requestor's services, "such that the free access would have no independent value to the Physicians apart from the services the Requestor provides." 2012 WL 7148096, at *3.

In considering whether the drug samples and supply kits had independent value to the physicians themselves, the court stated the 2003 OIG Guidelines note "if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer." *Id*. at 807 (quoting 2003 OIG Guidance, 68 Fed. Reg. 21731, 2003 WL 2010428, at *23737). The court noted Allergan's argument – that the free drug samples did not qualify as remuneration because they were passed on to patients and thus had no "independent value" to the physicians themselves – had "some force" given the language of the 2003 OIG Guidance. *Wood*, 246 F. Supp. 3d at 807. However, the argument "ultimately [went] too far" and fell short at the motion to dismiss stage of the case. *Id.*

According to the court, the free samples included a topical steroid that was applied pre- and post-operatively, and thus Allergan's provision "could plausibly have subsidized surgical costs, increasing ophthalmologists' profit per surgery." *Id*. The court noted such profit maximization can constitute remuneration under the AKS. *Id*. (citing *United States ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 270 (D. Mass. 2016)). The court found the relator's allegations, at a minimum, raised a question, not suitable for resolution at the motion to dismiss stage, whether ophthalmologists would otherwise have had to cover the costs of the drugs, thus lowering their profits per surgery. *Wood*, 246 F. Supp. 3d at 807.

Regarding the other supplies, the court noted the complaint alleged the patient instruction sheets were generally regarded as a "necessity," "raising the plausible inference that physicians would otherwise have had to cover printing and shipping costs themselves." *Id.* at 808-09. With

respect to the prescription pads, "Allergan provided these goods only to ophthalmologists who agreed to prescribe its drugs (rather than its competitor's drugs), again raising the plausible inference that physicians would otherwise have had to purchase their own prescription pads—or certainly that they would have to purchase general prescription pads more often." *Id.* at 809. According to the court, "the fact that physicians consistently designed and ordered these supplies on Allergan's dime is evidence that they viewed them as having value." *Id.*

Relators assert Defendants' conduct at issue in this case is "far more problematic and raises greater conflicts of interest concerns than that" raised in the *Wood* case. (Docket Entry # 52 at pg. 11). According to Relators, "providing essential administrative support and nursing services that Prescribers and their staff would otherwise need to undertake has far greater independent value and is more likely to influence a prescription than providing free patient instruction sheets and prescription pads to prescribers and patients." *Id*. (internal quotations and citation omitted).

Defendants argue *Wood* is distinguishable. According to Defendants, *Wood* highlights no illegal conduct is alleged here because *Wood* involved free products instead of free product support services like the free nurse and reimbursement support services alleged here. However, the *Witkin* case, cited in *Wood*, did involve some such services and is instructive. In *Witkin*, the relator alleged Medtronic violated the FCA by, among other things, paying kickbacks and other illegal remuneration to physicians to induce them to prescribe Medtronic insulin pumps (iPro devices) to their patients. 189 F. Supp. 3d at 265. Central to the relator's kickback allegations were so-called "iPro clinics," which referred to sessions in a doctor's office in which diabetes patients were invited to be fitted with the iPro device to evaluate their current diabetes management. *Id.* at 269. The relator alleged Medtronic paid or offered remuneration by running the clinics in doctors' offices, often without

physician involvement (Medtronic paid nurses to staff the clinics), while promoting the ways in which the physician could bill Medicare for patient iPro clinic visits. *Id.*

The court agreed with Medtronic that "merely explaining to physicians the manner in which iPro services could be billed to Medicare did not in itself constitute an offer of remuneration by Medtronic," noting the OIG has indicated a manufacturer's reimbursement support services in connection with its own products have no independent value. *Id.* (citing 2003 OIG Guidance, 68 Fed. Reg. 23731, 2003 WL 2010428, at *23735). However, the court found Medtronic's alleged activity "a step removed from reimbursement support for a product user." *Witkin*, 189 F. Supp. 3d at 269. Specifically, the relator had alleged promotional activity regarding reimbursement rather than active support for a product user, and those promotional activities, combined with the allegation that Medtronic staff often ran iPro clinics at no cost to the host physicians and entirely independently of a physician or his or her staff, transformed "what would be an otherwise innocuous patient-promotion practice into an offer of remuneration to the physicians." *Id*. at 269-70. According to the court, "even a physician *legitimately* billing Medicare for properly-supervised iPro clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so." *Id.* at 270 (emphasis in original). The court found the relator had adequately alleged remuneration through the iPro clinics. *Id.*

With these cases in mind, along with the guidance from the OIG, the Court now considers whether Relators have plausibly alleged Defendants' free nurse and reimbursement support services programs eliminated an expense Prescribers would have otherwise incurred (i.e, have independent value to Prescribers).

Whether Relators plausibly allege Defendants eliminated an expense Prescribers would have otherwise incurred (i.e., have independent value to Prescribers)

Relators assert the FAC contains "ample allegations" that establish the free nurse and reimbursement support services do in fact provide independent value to the Prescribers because they eliminate substantial expenses the Prescribers would otherwise have to incur. Defendants assert the FAC ties the support programs to the Covered Products, and Relators' express acknowledgment that the alleged services were limited to the specific products "is fatal to any claim that the subject activities constitute unlawful remuneration to doctors under the AKS." (Docket Entry # 38 at pg. 11). The Court disagrees with Defendants' characterization of the FAC and outlines below the specific allegations in the FAC regarding the independent value the free nurse and reimbursement support services have to the Prescribers.[9]

Regarding the first alleged scheme, the FAC alleges as follows. Patients suffering from MS and cancer often require extra office time, training, and resources to manage their disease. (FAC, ¶ 93). "Seeking to exploit the needs of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe the Covered Products." *Id.* ¶ 94. As CI-2 explained, "[w]hen it was discovered that patients needed so much more than what they were getting, a golden opportunity appeared." *Id.*

Bayer's MS nurse educator program is called "Beta Plus" (as in "Betaseron"), and the nurse educators are referred to as "Beta Nurses." Bayer and Amgen's nurse educator program for Nexavar

[9] These allegations are also relevant to Defendants' arguments under Rule 9(b), discussed in more detail below.

is called "Nex Connect," and the nurse educators are sometimes referred to as "Clinical Support Specialists." Bayer's patient support program for Adempas is called "AIM." *Id.* ¶ 95. All three of these programs were/are available to patients across the United States. *Id*.

Bayer and Amgen's nurse educator patient trainings were one-on-one sessions between a nurse educator and a Prescriber's patient. *Id*. ¶ 96. The trainings were usually in the patient's home and the length of the trainings varied between forty minutes and an hour and a half. Patients could receive in-person training multiple times, depending on the patient's needs. Patients received telephonic follow-ups from nurse educators at scheduled intervals; for example, at two weeks, one month, two months, etc. In general, Betaseron patients received one in-person training from a nurse educator, while Nexavar patients were trained in-person twice. *Id.* Patient training sessions included training regarding disease state, answering patient questions, assisting with insurance coverage, and teaching on how to administer the Covered Products. *Id*. ¶ 97.

Prescribers were encouraged to enroll all patients using the Covered Products into these patient support programs so that the nurse educators could begin to directly manage these patients and free the Prescriber from the time and expense of doing so. *Id*. ¶ 98. CI-2, a Beta Nurse, offered her nurse educator services to Prescribers by saying "consider me being the eyes and ears of your clinic, but in [the patient's] home. So I can give you information and feedback and observations that you can't make because you only see them when they come in and they only share as much as they want to share with you. When I meet with them, in their homes, I get more information, even if it's just by observation." *Id*. ¶ 100. CI-2 further explained that she persuaded Prescribers by saying, "Give me one patient. Let me prove to you that I can make a difference, and if that works, if that made a difference, then we'll go from there." *Id.*

The nurse educator programs provide a valuable, tangible benefit to Prescribers. *Id*. ¶ 102. CI-1, another Beta Nurse, stated her role was "like another nurse for the doctor . . . we were part of the team, where doctors could call us and we could call the doctors." *Id*. She explained that her role was very interactive with the Prescriber; nurse educators and Prescribers would collaborate when treating patients. *Id*. CI-2 elaborated on the benefit to Prescribers as follows:

> Well, going back to that 'give me one patient. Let me prove to you that I can make a difference,' . . . [Prescribers] gave [nurse educators] their most difficult patient. The one that's always calling them. The one that always has questions about side effects. The one that wants to come in and be seen all the time. If you can get that patient and help manage that patient, it saves [Prescribers] from getting phone calls from the patient, returning phone calls for that patient, guiding the patient on how to manage their side effects, or needing to come in excessively. So it saves office time. It saves them consequently then, money because they're not spending time reassuring and reiterating the message that they've already told this patient who just is needy and either isn't remembering it or just has excessive needs. You help manage those patients so that the office doesn't have to.

Id. ¶ 103.

Both CI-1 and CI-2 also explained that part of their role was to help patients overcome "needle phobia," as Betaseron is a self-injectable medication. *Id.* ¶ 104. Further, CI-3, an MS drug rep, also believed the Betaseron nurse educator services were a tangible benefit to Prescribers as evidenced by the "sheer number of Prescribers who utilized or are utilizing nurse educator services." *Id*. CI-3 estimated that 95% of Prescribers who prescribed Betaseron also utilized the nurse educator services. *Id.*

CI-5, a Nexavar nurse educator, explained the benefit to Prescribers as follows:

> [T]here were a couple of offices that had such a great number of patients that usually . . . would do the initial training very quickly right there in the office at the time of the visit. And then, if that patient needed additional training, . . . [Prescribers] just kept a list and at the end of the week they would send me the list and say, '[Y]ou may

> want to just touch base with each of them [patients].' . . . [T]hat would save [Prescribers] time and money . . . . They would tell the patient, 'You're going to get a call from the Nexavar nurse. She is going to make sure you're feeling okay and go over everything. If you needed this training or help or follow up, this is her number you can call her.'

Id. ¶ 105.

CI-5 further stated that "when [Prescribers are] familiar with the fact that [Bayer and Amgen] have this great nursing service that will walk the patients and hold their hands through the process, where they can . . . write the script [and] take a step back . . . instead of [dealing with] the patient calling continuously with questions of confusion, that's a big positive for many offices." *Id.*

According to the FAC, the "nurse educators are effectively free employees given to Prescribers in exchange for the Prescribers' commitment to recommend the Covered Products over competing products." *Id.* ¶ 107. Bayer and Amgen, with the assistance of Lash and Amerisource, enabled Prescribers to "eliminate an expense that [they] would have otherwise incurred" if they directly employed the nurse educators or provided the services themselves; thus, Bayer and Amgen's free nurse services scheme violates the AKS. *Id.*

Regarding the third alleged scheme, the FAC alleges as follows. To induce recommendations of Betaseron and Nexavar over competing products, Bayer and Amgen, with the assistance of Lash, offered a third type of kickback: free reimbursement support services for Prescribers who wrote prescriptions for Betaseron or Nexavar. *Id.* ¶ 146. "This remuneration was a tangible in-kind benefit that greatly reduced, and in some instances eliminated, Prescribers' administrative costs related to prescribing Betaseron and Nexavar." *Id.* ¶ 147. Lash highlighted its Support Services on its website:

> Our dedicated site coordinators strive to become an *extension of the provider's team*, with a single point-of-contact case management approach that streamlines and optimizes reimbursement processes.

Id. ¶ 149 (emphasis in original).

According to the FAC, the Bayer and Amgen reimbursement support services were the "carrot" (remuneration) "dangled to induce Prescribers to prescribe Betaseron and Nexavar to their patients." *Id.* ¶ 150. "Support Services have a great value to Prescribers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services also help increase profitability, particularly for office-based Prescribers, who derive most of their revenue from billing 15, 30, and 45-minute units of service provided to patients during office visits." *Id.* ¶ 151.

The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. *Id.* ¶ 152. Medicare pays over $11 billion each year for E/M services alone. *Id.*

When an office-based Prescriber receives payment for an E/M service, the payment is intended to compensate the Prescriber for medical care given *and* administrative tasks associated with that patient's care. *Id.* ¶ 153. These tasks include conducting a patient's prescription drug insurance benefit verification, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, conducting telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests, and, where necessary, obtaining prior authorizations, and managing the resulting paper trail. *Id.* Despite these enormous administrative costs and expenses, office-based Prescribers are not

permitted, under federal or state regulations, to directly charge patients a fee for any of these services. *Id*. Instead, Prescribers get paid for these services indirectly through the E/M unit charge. *Id.*

One way to earn more profit is by reducing the administrative costs associated with prescribing drugs. *Id.* ¶ 155. If a Prescriber can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a Prescriber's prescribing behavior. *Id.*

While pitching Prescribers, Bayer and Amgen sales reps emphasize that, if the Prescribers prescribed Betaseron or Nexavar, Bayer and Amgen would provide the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug. *Id.* ¶ 157. Bayer and Amgen sales reps further emphasize the cost and expenses normally associated with managing a patient's prescription would be shifted to Bayer and Amgen, thereby increasing the Prescriber's bottom line. *Id.* CI-6 specifically noted that his message to Prescribers included noting that his company was there to "make it easy for their reimbursement services within the [Prescriber's] office." *Id.* ¶ 158.

If the Prescriber recommends Betaseron or Nexavar, the time-consuming benefit verification task for these drugs is handled by Lash's staff, rather than the Prescriber's staff. *Id.* ¶ 159. Each day, Lash's office receives requests from Prescribers to perform benefit verifications for patients. Each request is immediately forwarded to a verification specialist. *Id.* ¶ 160. The specialist verifies the source of the patient's primary and secondary insurance benefits and contacts that insurer to verify the nature and extent of the patient's drug benefit coverage. For Medicare patients, coverage determinations tend to be particularly cumbersome and time-consuming given the complexity of many Part D plans. *Id*.

In addition to verifications and coverage determinations, Bayer and Amgen also provide prior authorization services. *Id.* ¶ 161. Bayer and Amgen also provide a service to appeal authorization and coverage denials. *Id.* ¶ 162. The process of obtaining a prior authorization and/or appealing a denial requires direct input from the Prescriber regarding the patient's medical history, clinical and laboratory findings, and other information to establish the patient's medical necessity for a particular drug. *Id.* ¶ 163. Although these steps ordinarily require substantial time and expertise from the Prescriber and their staff, Prescribers are not permitted to charge a fee separate from the E/M unit charge. "Bayer and Amgen arranged for personnel to handle prior authorizations and appeals, giving a clear advantage *and* tangible financial incentive to Prescribers who choose to prescribe Betaseron and Nexavar over competitors." *Id*. (emphasis in original).

CI-3, a Betaseron drug rep, estimated that 95% of the Prescribers who prescribed Betaseron utilized Lash's Support Services. *Id.* ¶ 164. CI-6, a Nexavar drug rep, estimated that 70% of the Prescribers who prescribed Nexavar utilized the reimbursement support services. *Id.* CI-4, a reimbursement support services representative for Betaseron, believes that offering reimbursement support has a positive net impact in terms of prescriptions and refills because it "helps [Prescribers] not have to worry too much about if that patient can actually have that medication because you have specialists behind you who [are] contacting the insurance company." *Id.* ¶ 165.

According to the FAC, the reimbursement support services have real value to Prescribers. *Id.* ¶ 167. Without them, Prescribers would have to use their own staff and resources or outsource the support services to a private vendor. Bayer and Amgen give Prescribers a means to "outsource" this function without any direct or indirect cost to the Prescriber, but only if the Prescriber prescribes Betaseron or Nexavar. *Id.*

The Court must construe all well-pleaded facts liberally in favor of the party opposing the motion. *Scheuer v. Rhodes,* 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974). The term "any remuneration" in the AKS suggests an expansive reading of the form of any kickback directly or indirectly, as opposed to a narrow reading that would exclude the allegations here. 42 U.S.C. § 1320a-7b (b)(1 & 2)(A). Having carefully reviewed this matter, the Court finds Relators have adequately pleaded Defendants set up a system whereby physicians received something of independent value if they prescribed the Covered Products. At a minimum, the allegations raise a question as to whether the free nurse and reimbursement support services provided by Defendants eliminated an expense Prescribers would otherwise have had to incur. *See Witkin*, 189 F. Supp. 3d at 270 ("[E]ven a physician *legitimately* billing Medicare for properly-supervised iPro clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so.").

The Court now considers whether the white coat marketing by nurse educators theory alleges unlawful remuneration was paid to nurse educators.

b. Whether the white coat marketing by nurse educators theory alleges unlawful remuneration was paid to nurse educators

Defendants' assertions

According to Defendants, Relators do not allege Defendants' payments to the nurse educators for merely educating doctors and patients about the medicines violate the AKS. Rather, under this second theory, Relators allege a violation of the AKS based upon salary payments to nurse educators for the provision of educational services. Defendants assert this legal theory is not sound, and even

if it were, it is not supported by the FAC's factual allegations and thus fails to plausibly allege this AKS violation theory.

Specifically, Defendants argue Relators' assertion that the nurses recommend the Covered Products is based entirely on a "mere inference that Relators argue should be drawn from other identified fact allegations," but those other fact allegations "plainly do not reasonably support any such inference." (Docket Entry # 38 at pg. 12). Defendants assert all of the facts on which the FAC relies to support Relators' conclusion that nurse educators recommended the medicines are consistent with merely educating about those products as opposed to recommending them.

Whether Relators' white coat marketing by nurse educators theory is a sound one

According to Defendants, Relators' legal premise—that "the AKS prohibits pharmaceutical companies from paying non-employees to 'recommend' its drugs to others" (FAC, ¶ 114)—is simply wrong. Defendants point out the AKS has both statutory and regulatory "safe harbors" expressly permitting pharmaceutical companies to engage non-employees to provide services. *See* 42 U.S.C. § 1320a-7b(b)(3)(C); 42 C.F.R. § 1001.952(d) (listing relevant factors in evaluating "personal services and management contracts" for non-employee agents, including those engaged in promotion). Defendants further contend the 2003 OIG Guidance "makes crystal clear that merely paying a third-party contractor to 'recommend' a product, without more, is not a violation of the AKS." (Docket Entry # 38 at pg. 14) (citing 68 FR 23731, 2003 WL 2010428, at *23739 ("Sales agents, whether employees *or independent contractors*, are paid *to recommend* . . . the items they offer for sale on behalf of the pharmaceutical manufacturer they represent. *Many arrangements can be structured to fit in the* employment or *personal services safe harbor*.") (emphasis added by Defendants)).

A number of statutory and regulatory safe harbors protect certain business arrangements that might otherwise violate the AKS. *See* 42 U.S.C. § 1320a–7b(b)(3)(A)–(J); 42 C.F.R. § 1001.952. These safe harbors "apply only in very specific instances" to "exempt[ ] only a small subset of such transactions." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (citations omitted). "To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute." *Id.* (citing OIG Compliance Program for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734 (May 5, 2003)). These safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial. *See United States v. Norton,* 17 Fed.Appx. 98, 102 (4th Cir. 2001) (unpublished). The failure to comply with a safe harbor is not a per se violation of the AKS, but the defendants must prove strict compliance with a safe harbor to avoid liability for an arrangement that might otherwise violate the statute. *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014).

The Court finds without merit Defendants' argument the FAC's allegations regarding white coat marketing by nurse educators fall within a safe harbor and thus are wholesale exempt from AKS scrutiny. Relators point out the "personal services" safe harbor set forth in 42 C.F.R. § 1001.952(d) covers only services that "do not involve the counseling or promotion of a business arrangement or other activity that violates any State of Federal law." In the FAC, Relators allege the OIG refers to the practice of utilizing healthcare providers, like nurses, to promote particular drugs as "white coat marketing," and has warned against the practice as follows.

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as 'white coat' marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an

> exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services. . . .

(FAC, ¶ 112) (quoting OIG Advisory Opinion 11-08, at 6, 2011 WL 4526111 (Jun. 14, 2011)).

Relators have alleged conduct that arguably violates the AKS – paying direct remuneration to Providers– and, as urged by Relators, this conduct is not immunized by using an intermediary to recommend products.

Whether Relators plausibly allege facts from which it could be inferred the nurse educators recommended the Covered Products as opposed to providing education services

According to Defendants, the gist of Relators' theory that the nurse educators recommended the Covered Products is that the nurse educators' access to doctors and nurses put them "in a prime position to recommend" those medicines and to thus further Defendants' sales objectives. (Docket Entry # 38 at pgs. 13-14). Defendants assert alleging mere "opportunity and motive" does not reasonably support an inference of action. Defendants argue the allegations and alleged statements by the CIs are inconsistent with any inference that the nurses recommended products as opposed to providing education services. The Court disagrees.

The FAC alleges as follows. Bayer and Amgen paid remuneration to nurse educators to recommend the Covered Products over competing products to Prescribers and patients. (FAC, ¶ 111). The nurses were likely to be viewed by Prescribers as better credentialed and more credible than traditional drug reps, and, thus, they were more likely to gain access to Prescribers and their staff. *Id.*

According to the FAC, Bayer and Amgen contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to

appear to be independent. *Id*. ¶ 115. Bayer, Amgen, Amerisource, Lash, and Ashfield designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to Prescribers. *Id*. Although the nurses were independent contractors and were purportedly "educators," they were expected to and did recommend the Covered Products. *Id.* ¶ 116. This conclusion is compelled by numerous facts Healthcare Group uncovered during its investigation.

Bayer and Amgen invested heavily in training nurse educators how to gain access to Prescribers and promote the Covered Products because Bayer and Amgen's ultimate goal was to drive drug sales. *Id*. ¶ 117. CI-1 explained she was trained on what to say to Prescribers because "we were able to actually make visits without the sales [rep] and that's why it was more important for us to know the correct things to say." *Id*. ¶ 118. CI-1 would often report back to the Prescriber after a patient's training, so she was taught how to use that interaction to promote Betaseron. She noted she "could not compare other medications, but we could talk about all the benefits and the things that we saw that the patients were able to benefit from the drug [Betaseron]." Similarly, CI-2, a Beta Nurse, indicated she was trained on how to overcome Prescriber and staff objections. *Id*.

Relator Green was trained in person for an entire week at Bayer's headquarters in New Jersey, with the focus being on sales techniques. *Id*. ¶ 118. The trainees were from all over the United States, including Texas, California, Boston, Atlanta, North Carolina, and Chicago. *Id.* At the end of the week, the trainees, including Green, had to demonstrate how they would market the product to the Prescribers. *Id*. Through role-playing exercises, the trainers played the role of the Prescribers. *Id*.

Once trained, Bayer and Amgen selectively deployed nurse educators to target Prescribers and facilities with high potential to prescribe the Covered Products. *Id*. ¶ 121. To maximize the chances of success, the nurse educators coordinated with Bayer and Amgen drug reps and would often accompany the drug reps on sales calls. *Id.* Green was given a list of approximately 150 Prescriber offices and was expected to collaborate with the sales team. *Id*. ¶ 122.

Once trained, nurse educators immediately began to gain access and infiltrate Prescriber offices and facilities. *Id*. ¶ 125. For example, CI-1, a Beta Nurse, explained: "It was such a big plus for the sales rep to be able to travel with a Beta nurse. So, they wanted us out there as soon as possible to meet any new doctors . . . ." *Id*.

Given their training, education, and experience, nurse educators were able to gain access to potential Prescribers in some circumstances where drug reps could not. *Id*. ¶ 125. In Green's experience, it was much easier to gain access to Prescriber offices because she was a nurse educator as opposed to a sales rep. *Id*. Green would often provide lunches at Prescriber offices and discuss Adempas while the staff ate. Green would leave information about the drug and continue to follow up, particularly with those Prescribers that had patients with pulmonary hypertension or that expressed interest. *Id*.

In CI-5's experience, "very often now . . . doctor's offices have posted right on their doors 'we will not see drug reps' . . . . [S]o often, I can get my foot in the door . . . . I've worked with many of the nurses in my area . . . and the doctors and sometimes it's just [that the Prescribers] like dealing with another health care practitioner instead of somebody that they feel [is] trying to sell them something . . . ." *Id*. ¶ 129. CI-6, a Nexavar drug rep, agreed. "It's getting more difficult now to get in to the oncology offices primarily because of the Sunshine Act . . . depending on the individual

practice. So any time you can have access from a nursing point of view that really helps you with . . . promoting your product in that particular practice." *Id.* ¶ 130.

The real mission of the nurse educators was to increase prescriptions of Bayer and Amgen Covered Products. *Id.* ¶ 131. The nurse educators generally did not discuss competitors. *Id.* ¶ 132. A true nurse educator's role would inherently include a discussion of the many treatment options for MS or cancer. *Id.* ¶ 133. However, these nurse educators focused on the benefits of the Covered Products. Indeed, according to Green, part of the goal was to get Prescribers to switch to Adempas from another competing drug. *Id.*

Amerisource and Lash nurse educators also promoted Betaseron and Nexavar directly to MS and cancer patients. *Id.* ¶ 140. As with the Prescribers, by purporting to educate patients, white coated nurse educators would be in a prime position to recommend and promote Betaseron and Nexavar directly to these patients. *Id.* Importantly, these encounters were direct nurse-to-patient contacts that, in general, took place at lunch or dinner programs and health fairs. *Id.* ¶ 141. These patient education sessions could be used to actively convert patients from their current medications to Betaseron or Nexavar. *Id.*

According to Relators, Bayer and Amgen's nurse educator programs were nothing more than a scheme to drive prescriptions for the Covered Products. *Id.* ¶ 145. By providing remuneration to Lash, Amerisource, and Ashfield to employ and deploy "white coated" nurses to recommend the Covered Products, Defendants violated the AKS. *Id.* The AKS proscribes the conduct, *i.e.,* payment or offer of payment to "any person" in exchange for a recommendation or referral. According to the FAC, it is immaterial if the payee receiving the remuneration in exchange for recommending a drug is a doctor (who can recommend by writing a patient a prescription) or some other payee, such as

a nurse, a medical assistant, a patient recruiter, or a runner, who can recommend the drug to a patient or a Provider. *Id.* Relators assert Defendants violated the AKS by compensating nurses in part to recommend the Covered Products. *Id.*

The Court finds the above allegations, including those regarding the sales training of the nurse educators, are sufficient at this stage to support an inference that the nurses recommended products as opposed to merely providing education services. The Court recommends Defendants' Rule 12(b)(6) motion to dismiss Counts 1 and 2 because the FAC fails to plead falsity be denied.

2. Whether Counts 1 and 2 should be dismissed because the FAC fails to plead the essential element of scienter

Defendants further assert Relators fail to plead sufficient facts to demonstrate the necessary FCA element that each defendant "knowingly" caused the submission of false claims. The Fifth Circuit has explained that "[t]hough the FCA is plain that 'proof of specific intent to defraud' is not necessary, [the mens rea] requirement is not met by mere negligence or even gross negligence." *Longhi*, 575 F.3d at 468 (quoting *United States ex rel. Farmer v. City of Houston,* 523 F.3d 333, 338 (5th Cir. 2008) (internal citation omitted)). Thus, Relators must demonstrate Defendants had (1) actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information provided, or (3) acted with reckless disregard of the truth or falsity of the information provided to the Government. *Longhi*, 575 F.3d at 468.

As discussed previously, the intent element of the FCA may be alleged generally, but "simple allegations that defendants possess fraudulent intent will not satisfy Rule 9(b)." *Dorsey v. Portfolio Equities, Inc*., 540 F.3d 333, 339 (5th Cir. 2008) (quoting *Melder v. Morris,* 27 F.3d 1097, 1102 (5th Cir.1994)). "The plaintiffs must set forth *specific facts* supporting an inference of fraud." *Id.*

Whether Defendants submitted, or caused to be submitted, a "false claim" depends on whether the AKS was violated. *United States ex rel. Jamison v. McKesson Corp.*, No. 2:08CV214-SA-JMV, 2012 WL 487998, at *5 (N.D. Miss. Feb. 14, 2012). The AKS requires the defendants act "willfully, that is, with the specific intent to do something the law forbids." *United States v. Gibson*, 875 F.3d 179, 188 (5th Cir. 2017), *cert. denied*, No. 17-8959, 2018 WL 2290847 (June 18, 2018).

Defendants assert they cannot "knowingly" cause another to submit a false claim on the basis of an underlying legal violation where Defendants' conduct complied with an objectively reasonable interpretation of the law. (Docket entry # 38 at pg. 15) (citing *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 287–88 (D.C. Cir. 2015) ("Consistent with the need for a knowing violation, the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. . . . Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations.")). According to Defendants, Relators have failed to plead any facts demonstrating Defendants actually knew their product-specific support services violated the AKS; rather, their free nurse and reimbursement support services complied with an objectively reasonable interpretation of AKS case law and relevant OIG guidance documents.

Regarding the second theory, even if Relators had sufficiently pleaded Defendants paid nurse educators to recommend the Covered Products (which Defendants contest), Defendants assert Relators cannot establish that "promotional" activity by the nurse educators would violate the AKS and therefore that Defendants knew those acts violated the AKS. Again, Defendants rely on the statutory and regulatory safe harbors which allow pharmaceutical companies to utilize non-employees in promotional activities. Defendants acknowledge the use of health care professionals in marketing activity is closely scrutinized, but argues the OIG has not stated such activity is

"categorically prohibited." (Docket Entry # 38 at pg. 17). According to Defendants, this "ambiguity allows for more than one reasonable interpretation of the law and, even assuming Relators' allegations as true, prohibits as a matter of law any finding that Defendants knowingly violated the FCA under Theory Two." *Id*.

As urged by Relators in their response, Defendants' "ambiguous guidance" argument is unavailing. (Docket Entry # 52 at pg. 15). As an initial matter, all of the advisory opinions OIG has issued are limited to the "specific arrangement[s] described in [each] letter" and none has "applicability to other arrangements, *even those which appear similar in nature and scope.*" *Id*. (quoting OIG Advisory Opinion 00-10, 2000 WL 35747420, at * 11 (emphasis added by Relators)). The OIG encourages "any marketplace actor to seek its own advisory opinion regarding its own conduct." (Docket Entry # 52 at pg. 15) (citing 42 C.F.R. § 1008.11). According to Relators, Defendants did not seek OIG's guidance in implementing the challenged schemes, and this alone is sufficient to infer scienter.

Recognizing it is true that FCA liability does not attach to reasonable but erroneous interpretations of the law, Relators assert the statute requires a defendant to actually come to that reasonable but incorrect conclusion. (Docket Entry # 52 at pg. 16) (quoting *Waldmann v. Fulp*, 259 F. Supp. 3d 579, 629 (S.D. Tex. 2016)). In *Waldmann*, 259 F. Supp. 3d 579, 629 (S.D. Tex. 2016), the defendants argued they could not have possibly known of any AKS violation because they believed that Santos was a bona fide employee and therefore fell under the AKS safe harbor provision. According to the defendants, to prove they knowingly submitted false claims, the relators must provide evidence that it was unreasonable, at the time the claims were submitted, for them to believe that Santos was a bona fide employee of RedMed. The court noted the statute requires a

defendant to actually come to that reasonable but incorrect conclusion, and the defendants did not argue they undertook any effort to determine whether Santos was a bona fide employee of RedMed. *Id*. The evidence before the court, when viewed in the light most favorable to the relators, supported a reasonable inference that the defendants did not make a good-faith determination, pursuant to a reasonable interpretation of the AKS, that Santos was a bona fide employee under the safe harbor provision. *Id.* at 630.

Notably, the court in *Waldmann* decided the issue at the summary judgment stage. Relators assert the cases relied upon by Defendants in their motion to dismiss are inapposite because the defendants in those cases "demonstrated through a *developed record* their actual belief, concurrent with the accused activity, that their actions were legally permissible." (Docket Entry # 52 at pg. 16 & n. 4) (emphasis in original) (citing *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 289 (D.C. Cir. 2015) (overturning a jury decision); *Safeco Ins. Co. of Am. v. Burr,* 551 U.S. 47, 52 (2007) (affirming dismissal on summary judgment); *United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 982 (D.C. Cir. 2008) (affirming dismissal on summary judgment); *United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 921 (S.D. Tex. 2007) (granting summary judgment)).

The majority of courts have held it is inappropriate to decide a scienter issue, e.g. whether the defendants had a "good faith interpretation of the statute" that would negate the intent necessary for an FCA violation, at the pleading stage of the litigation. *United States ex rel. Banigan v. Organon USA, Inc*., No. CIV.A. H-08-3314, 2013 WL 4786323, at *2 (S.D. Tex. Sept. 6, 2013) (citing *United States ex rel. Wilkins v. N. Am. Constr. Corp.,* 173 F. Supp. 2d 601, 639 (S.D. Tex. 2001), *overruled on other grounds,* 575 F.3d 458, 469 (5th Cir.2009); *United States v. Honeywell Int'l Inc.,* 798

F.Supp.2d 12, 22–23 (D.D.C.2011) (scienter may be examined on summary judgment, but not on a motion to dismiss)); *see also Wood*, 246 F. Supp. 3d at 829 (finding that defendants' "reasonable interpretation" defense did not warrant dismissal, noting that "[a]t a minimum, they raise questions of fact that cannot be resolved at this stage of the proceedings"); *United States ex rel. Nevyas v. Allergan, Inc*., No. 09-432, 2015 WL 4064629, at *6 (E.D. Pa. July 2, 2015) (defendant's "reasonable interpretation of the law and applicable regulatory framework may well be a defense to liability, but it is not appropriate at the motion to dismiss stage when there are reasonable interpretations to the contrary"); *United States ex rel. Pasqua v. Kan-Di-Ki LLC*, No. CV 10-965-JST, 2012 WL 12895229, at *7 (C.D. Cal. June 18, 2012) (noting that "while ambiguity is relevant to the scienter inquiry, it does not preclude a finding of liability under the FCA unless no issues of fact remain" regarding the defendant's state of mind). The Court disagrees with Defendants that the regulatory framework and OIG guidance preclude a finding of a "knowing" violation as a matter of law.[10] Defendants' reasonable interpretation of the law argument does not warrant recommending dismissal at the motion to dismiss stage.

Although fraud claims are subject to a heightened pleading standard, a relator "may satisfy the FCA's scienter requirement with general allegations, as long as he sets forth specific facts supporting an inference of fraud." *United States ex rel. Woodard v. DaVita, Inc*., No. 1:05-CV-227, 2011 WL 13196556, at *8 (E.D. Tex. May 9, 2011). The inference may be drawn by alleging facts showing a defendant's motive or "by identifying circumstances that indicate conscious behavior on the part of the defendant . . . ." *Tuchman v. DSC Communications Corp.,* 14 F.3d 1061, 1068 (5th

[10] The Court is not convinced Relators' interpretation of the OIG guidance is unsupported and unreasonable as urged by Defendants in their reply. (Docket Entry # 66 at pg. 7 n. 7).

Cir. 2003). In *Woodard*, the relator alleged particular facts regarding the defendant's process of capturing and administering overfill to patients and also generally asserted the defendant acted in knowing violation of § 3729. 2011 WL 13196556, at *8. The court declined to dismiss the overfill claim. *Id*.

Here, the FAC similarly contains both general allegations that Defendants acted in knowing violation of the FCA and AKS and allegations from which a reasonable inference of intent to defraud the government can be inferred. The FAC alleges Defendants are aware of the prohibitions of the AKS. (FAC, ¶¶ 8-13). The FAC plausibly alleges Defendants disregarded those prohibitions in order to maximize profit. *See, e.g.*, *id*. ¶ 14 ("Although Bayer and Amgen, as well as their co-defendants, knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote the Covered Products, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace."), ¶ 85 ("Here, the claims submitted for the Covered Products violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above programs."), ¶ 115 ("In an attempt to circumvent the law, Bayer and Amgen contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to appear to be independent."); ¶ 145 ("By providing remuneration to Lash, Amerisource, and Ashfield to employ and deploy 'white coated' nurses to recommend the Covered Products, the Defendants violated the AKS.").

Relators have described Defendants' motives – driving profits through increased prescriptions. *See, e.g.*, *id*. ¶ 94 ("Seeking to exploit the needs of Prescribers and healthcare

organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe the Covered Products."); ¶ 99 ("In most cases they'll go, 'Well, we [Prescribers] don't have the time to be able to [do patient training] for our patients.' And a lot of times they'll talk to the sales people that *they're prescribing specifically to get a beta nurse*."); ¶ 131 ("The nurse educators were tasked with promoting Bayer and Amgen Covered Products. The real mission of the nurse educators was to increase prescriptions of Bayer and Amgen Covered Products."); *see also id.* ¶¶ 88, 108, 146.

The FAC also describes the nature of the financial benefit the nurse and reimbursement support services confer on providers. *See, e.g.*, *id*. ¶ 98 ("Prescribers were encouraged to enroll all patients using the Covered Products into these patient support programs so that the nurse educators could begin to directly manage these patients and free the Prescriber from the time and expense of doing so."); ¶¶ 100-06 (describing the tangible benefit the nurse educator program conferred on Prescribers); ¶ 107 ("The nurse educators are effectively free employees given to Prescribers in exchange for the Prescribers' commitment to recommend the Covered Products over competing products."); ¶¶ 151-167 (describing the tangible benefits reimbursement support services conferred on Prescribers).

The FAC also alleges the white coat marketing by nurse educators program was orchestrated by Defendants to unlawfully promote Bayer and Amgen products and that the nurse educators were compensated for their promotional activities. *See*, *e.g.*, *id.* ¶ 115 ("Although the nurses were independent contractors and were purportedly 'educators,' they were expected to and did recommend the Covered Products."); ¶ 117 ("Bayer and Amgen invested heavily in training nurse educators how

to gain access to Prescribers and promote the covered products. This training was a *vital* component of Bayer and Amgen's scheme because Bayer and Amgen's ultimate goal was to drive sales."); ¶¶ 118-120 (describing how nurse educators were hired and trained to promote Defendants' drugs as part of their job responsibilities); ¶¶ 121-145 (setting forth the evidence demonstrating that the nurse educators were expected to and did in fact promote Defendants' products in contravention of the prohibition on white coat marketing).

The Court finds in the Rule 12(b)(6) context Relators have alleged sufficient facts to satisfy the FCA's scienter requirement. The FAC contains numerous plausible allegations describing in detail the planning, execution, and goals of the alleged fraudulent schemes at the heart of Relators' FCA claims. "These

schemes involved five different businesses, numerous nurses and support services staff, and were executed on a national scale at Bayer and Amgen's expense." (Docket Entry # 52 at pg. 22). Viewing the allegations in the light most favorable to Relators, the FAC supports a reasonable inference that Defendants had the intent of inducing Prescribers to prescribe Bayer and Amgen products in exchange for the benefits provided by Defendants. The allegations further support an inference that Defendants knew, or acted with deliberate indifference of or in reckless disregard to, the submission of tainted false claims.

3. Whether Counts 1 and 2 should be dismissed because the FAC fails to plead the essential element of causation

a. Defendants' assertions

As an initial matter, Defendants assert Relators' own allegations suggest the prescription of the Covered Products was caused by factors other than any alleged remuneration. The confidential interviewees from Relator Health Choice Group's investigation acknowledge the medicines are

"beneficial" and the data "clearly show[s]" the medicines are superior to competing drugs. (FAC ¶¶ 137, 143). Defendants contend, without additional facts that are not found in the FAC, causation is speculative.

b. Applicable law

To state an AKS-based FCA claim, Relators also must allege facts to show Defendants' challenged actions "actually caused . . . physicians to prescribe" the medicines and that those prescriptions were then reimbursed by the Government. *See United States ex rel. King v. Solvay Pharmaceuticals, Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("[I]t would be speculation to infer that compensation for professional services legally rendered *actually caused* the physicians to prescribe [defendant's] drugs to Medicaid patients.") (emphasis added). The relator must "sufficiently link" the payment of remuneration "to a referral, patient, or claim." *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *24 (N.D. Tex. June 20, 2016), *reconsideration denied sub nom. U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-0604-M, 2017 WL 5483747 (N.D. Tex. Nov. 14, 2017). Mere temporal proximity of the remuneration to the claims, or statistical probability, is not enough. *Id*. at *25 ("The mere fact that 93% of Defendants' patients are Medicare patients is not sufficient to show Defendants submitted claims that falsely certified compliance with the AKS.").

c. Discussion

In *United States ex rel. Wilkins v. United Health Grp., Inc.*, the Third Circuit Court of Appeals concluded the appellants, in stating a plausible claim for relief at the Rule 12(b)(6) stage of the proceedings, need not allege a relationship between the alleged AKS violations and the claims appellees submitted to the government. 659 F.3d 295, 313 (3d Cir. 2011). According to the Third

Circuit, the complaint was sufficient to survive a Rule 12(b)(6) motion to dismiss because the appellants had pleaded the "appellees knowingly violated the AKS while submitting claims for payment to the Government under the federal health insurance program." *Id*. The court emphasized it was not reviewing the claims under the particularized pleading standards of FED. R. CIV. P. 9(b).[11] *Id*. at 313 n. 20.

Here, the FAC is sufficient to survive a Rule 12(b)(6) motion to dismiss because Relators have pleaded Defendants knowingly violated the AKS while submitting claims for payment to the Government under the federal health insurance program. The Court reaches a different result when reviewing the claims under the particularized pleading standards of FED. R. CIV. P. 9(b).

4. Conclusion

For the foregoing reasons, the Court finds Relators have alleged sufficient facts to state claims for which relief can be granted under both provisions of the FCA. "However, [Relators'] claims rely heavily on inferences and statistical extrapolations that, while sufficient to satisfy Rule 12(b)(6), may not be considered sufficient to satisfy the pleading requirements of Rule 9(b)." *United States ex rel. Nowak v. Medtronic, Inc*., 806 F. Supp. 2d 310, 351 (D. Mass. 2011). Before

[11] The appellees moved to dismiss the complaint under FED. R. CIV. P. 12(b)(6) for failure to state a claim upon which relief could be granted and FED. R. CIV. P. 9(b) for failure to plead fraud with particularity. However, the district court granted the appellees' motion for failure to state a claim and therefore did not address the appellees' alternative argument for dismissal that appellants failed to plead their claims with the particularity that Rule 9(b) requires. The district court dismissed the complaint because the appellants did not identify "even a single claim for payment to the Government." *See United States ex rel. Wilkins v. United Health Grp., Inc.,* No. 08-3425, 2010 WL 1931134, at *4 (D. N. J May 13, 2010), *aff'd in part, reversed in part and remanded by United States ex rel. Wilkins v. United Health Grp., Inc*., 659 F.3d 295, 301 (3d Cir. 2011).

considering those requirements, the Court will first address Defendants' limitations argument under Rule 12(b).[12]

VII. STATUTE OF LIMITATIONS

A. Defendants' assertions

Finally, Defendants assert a substantial portion of Relators' claims under the FCA and under the state FCA statutes are time-barred and should be dismissed. Specifically, Defendants assert any FCA violations based on claims submitted before June 19, 2011 (six years before the filing of the original complaint) are barred by limitations. *See United States ex rel. Ramadoss v. Caremark Inc*., 586 F.Supp.2d 668, 700 (W.D. Tex. 2008) ("Thus, the critical date for statute of limitations purposes for a relator is when the relator files a complaint."), *reversed in part by United States v. Caremark, Inc*., 634 F.3d 808 (5th Cir. 2011); *see also United States ex rel. Kennard v. Comstock Res., Inc*., No. 9:98-CV-266-TH, 2010 WL 2813529, at *1 n. 2 (E.D. Tex. July 16, 2010), *aff'd sub nom. U.S. ex rel. Wright ex rel. Wright v. Comstock Res., Inc*., 456 Fed. Appx. 347 (5th Cir. 2011) (The original complaint was filed on October 27, 1998, and the relators had stipulated they would not pursue false claims submitted prior to October 27, 1992 due to the six-year limitation period of 31 U.S.C. § 3731(b)(1)).

According to Defendants, Relators' claims under various state laws are also subject to limitations periods and are partially barred. Specifically, Defendants argue nineteen of the state laws at issue in this case contain substantially identical statutes of limitations and should also be restricted

[12] Defendants are entitled to make this argument in their Rule 12(b)(6) motion to dismiss "because a complaint that shows relief to be barred by the statute of limitations may properly be dismissed for failure to state a cause of action." *United States ex rel. Foster v. Bristol-Meyers Squibb Co.,* 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008) (citations omitted).

to claims submitted on or after June 19, 2011. Defendants assert the analogous FCA statutes in Arkansas and New Mexico have even shorter limitations periods.

B. Applicable law

> The text of the FCA's limitations provision states an FCA lawsuit may not be brought:
> (1) more than 6 years after the date on which the violation of [the FCA] is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with the responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

31 U.S.C. § 3731(b).

In the Fifth Circuit, *qui tam* FCA actions are governed by the limitations period found in § 3731(b)(1) when the government declines to intervene, as it did here. *See United States ex rel. Jackson v. Univ. of N. Texas*, 673 Fed. Appx. 384, 387 (5th Cir. 2016), *cert. denied sub nom. U.S. ex rel. Jackson v. Univ. of N. Texas*, 138 S. Ct. 59 (2017)*; see also Foster*, 587 F. Supp. 2d at 816 ("This Court has thoroughly considered the text of the statute, the legislative history, and the case law cited above. Having done so, the Court is of the opinion that actions brought by a *qui tam* relator are governed by the limitations period in § 3731(b)(1).").

The limitations period for FCA claims is computed from the date on which the violation is committed, *i.e*., the date of submission of the false claim, not the date of payment of a false claim. *United States v. Organon USA, Inc*., No. H-08-3314, 2013 WL 12142351, at *7 (S.D. Tex. Feb. 1, 2013) (citing *Smith v. United States*, 287 F.2d 299, 303-04 (5th Cir. 1961); *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409 (2005)). Defendants, as the parties asserting the statute of limitations defense, bear the burden of proving limitations bars Relators' claims. *See Frame v. City of Arlington*, 657 F.3d 215, 239 (5th Cir. 2011) (en banc).

C. Discussion

1. Federal FCA claims

Relator Health Choice Group filed this lawsuit on June 19, 2017, alleging Defendants' schemes continued at least through 2014, and up to present day. (FAC, ¶¶ 184-204). Regarding the breadth of Bayer and Amgen's kickback scheme, the FAC also alleges the scheme encompasses every Prescriber that, since at least 2006, received free nurse services paid for by Bayer or Amgen, received a visit from a nurse educator that purported to provide education concerning MS, cancer, and pulmonary hypertension on behalf of Bayer and Amgen, and/or received support services paid for by Bayer or Amgen. *Id*. ¶¶ 108, 184-86. The FAC further alleges "[s]ince at least 2006, Defendants' actions knowingly have caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs for Covered Products provided to beneficiaries as a result of Defendants' illegal marketing and quid pro quo arrangements," and those "false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid." *Id*. ¶ 188.

Relators do not dispute they are subject to a six-year statute of limitations. In their response in opposition to Defendants' motion, Relators assert the issue is premature because they "have not given any indication that they intend to pursue claims for FCA violations outside of the range of the six-year limitation period." (Docket Entry # 52 at pg. 37).

It is unclear from the FAC the timeframe for the false claims Relators are asserting. Accordingly, the Court cannot comfortably conclude any claims are time barred, and thus will not recommend the part of the motion to dismiss on statute of limitation grounds be granted at this juncture. *See Allen v. Beta Const*., 309 F. Supp. 2d 42, 48 (D.D.C. 2004) (citing *Firestone v.*

Firestone, 76 F.3d 1205, 1209 (D.C. Cir.1996) ("courts should hesitate to dismiss a complaint on statute of limitations grounds based solely on the face of the complaint . . . because statute of limitations issues often depend on contested questions of fact, dismissal is appropriate only if the complaint on its face is conclusively time-barred"). If warranted, Defendants can certainly move for summary judgment on limitations grounds on any claims ultimately asserted by Relators.

2. State FCA claims

In addition to the federal FCA claims, Relators have asserted causes of action under the analogous FCA statutes of thirty-one Plaintiff States (Counts 4-34, FAC ¶¶ 221-375). Defendants assert the applicable statute of limitations under each of twenty-one states FCAs is as short as, or shorter than the federal statute. Accordingly, Defendants argue any Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Vermont claims before June 19, 2011 are time-barred. *See King v. Solvay S.A.*, 823 F. Supp. 2d 472, 538 (S.D. Tex. 2011), *order vacated in part on reconsideration of other grounds*, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) (applying six-year limitations period to state law claims with statutes "substantially similar to the federal FCA limitations clause").

Regarding the states' statutes of limitation, the Court finds that further briefing and specificity as to each state's statute, its date of enactment and language, and interpretive case law are required before a ruling on time-bars can be made, and it is probably more appropriate on a motion for summary judgment. *See Organon*, 2013 WL 12142351, at *35. The Court recommends the motion to dismiss these claims on limitations grounds be denied at this stage of the litigation.

VIII. RULE 9(b) MOTION TO DISMISS COUNTS 1-2

A. Applicable law

Relators must plead their FCA claim with particularity, including each element of the alleged AKS violations. *See United States v. Paramedics Plus LLC*, No. 4:14-CV-00203, 2017 WL 4812443, at *4 (E.D. Tex. Oct. 25, 2017) ("In such a case, the elements of the AKS violation must also be pleaded with particularity under Rule 9(b), because they are brought as a FCA claim."). The Fifth Circuit applies Rule 9(b) to fraud complaints "with bite" and "without apology," but also recognizes Rule 9(b) "supplements but does not supplant Rule 8(a)'s notice pleading." *United States ex rel. Vavra v. Kellogg Brown & Root, Inc.,* 903 F. Supp. 2d 473, 484–85 (E.D. Tex.2011), *rev'd on other grounds,* 727 F.3d 343 (5th Cir. 2013) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009)). Rule 9(b) requires only "simple, concise, and direct" allegations of the "'circumstances constituting fraud,' which after *Twombly* must make relief plausible, not merely conceivable, when taken as true." *Grubbs*, 565 F.3d at 186 (quoting FED. R. CIV. P. 9(b)).

The court in *United States v. Medco Health Sys., Inc.*, No. CIV. 12-522 NLH AMD, 2014 WL 4798637 (D.N.J. Sept. 26, 2014) considered what must be alleged to satisfy the standards of Rule 9(b). The court provided the following summary of the different approaches:

> In *Foglia v. Renal Ventures Management, LLC,* 754 F.3d 153, 155–56 (3d Cir.2014), the Third Circuit explained that the 'Fourth, Sixth, Eighth, and Eleventh Circuits have held that a plaintiff must show "representative samples" of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors,' while the 'First, Fifth, and Ninth Circuits, however, have taken a more nuanced reading of the heightened pleading requirements of Rule 9(b), holding that it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.' *Foglia,* 754 F.3d at 155–56 (citations and quotations omitted). Considering that 'the purpose of Rule 9(b) is to provide defendants with fair notice of the plaintiffs' claims,' the Third Circuit adopted 'the more "nuanced" approach

> followed by the First, Fifth, and Ninth Circuits.' *Id.* at 156–57 (citations and quotations omitted).

2014 WL 4798637, at *6.

In *Grubbs,* the Fifth Circuit reversed the district court's dismissal of a *qui tam* suit alleging psychiatrists billed Medicare and Medicaid for services not performed. 565 F.3d at 185. *Grubbs* analyzed the Eleventh Circuit's decision in *United States ex rel. Clausen v. Laboratory Corporation of America, Inc*., 290 F.3d 1301 (11th Cir. 2002) requiring allegations of the "specific contents of actually submitted claims, such as billing numbers, dates, and amounts." *Id.* at 186. Rejecting this requirement, the court stated as follows:

> [T]he 'time, place, contents, and identity' standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act. We reach for a workable construction of Rule 9(b) with complaints under the False Claims Act; that is, one that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud. We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

Id. at 190. The Fifth Circuit established a relaxed standard by which Rule 9(b) is applied with flexibility in consideration of the specific circumstances of a case. *Id.*

Thus, to plead FCA liability predicated on AKS violations in the Fifth Circuit, relators need only allege the particular details of a scheme to offer kickbacks in order to induce referrals, coupled with reliable indicia leading to a strong inference that claims based on such referrals were actually submitted to the government. *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-CV-3396, 2014 WL 2618158, at *10 (S.D. Tex. June 12, 2014), *on reconsideration in part sub nom*. *Ruscher v. Omnicare Inc.,* No. 4:08-CV-3396, 2014 WL 4388726 (S.D. Tex. Sept. 5, 2014) (citing *United*

States ex rel. Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 667 (S.D. Tex. 2013), *aff'd sub nom. U.S. ex rel. Parikh v. Brown*, 762 F.3d 461 (5th Cir. 2014), *opinion withdrawn and superseded on reh'g*, 587 Fed. Appx. 123 (5th Cir. 2014), *withdrawn from bound volume* (Oct. 1, 2014), and *aff'd sub nom. U.S. ex rel. Parikh v. Brown*, 587 Fed. Appx. 123 (5th Cir. 2014)). While a plaintiff must still plead the circumstances constituting fraud with particularity, pleading the specific details of individual false claims is unnecessary. *Wagemann v. Doctor's Hosp. of Slidell, LLC*, No. 09-3506, 2010 WL 3168087, at * 4 (E.D. La. Aug. 6, 2010) (citing *Grubbs*, 565 F.3d at 190). "In other words, should a plaintiff allege a general scheme to defraud the government, when the scheme occurred, those involved, its mechanics, an explanation of how the claims were false, and a description of the billing system, the 'time, place, contents, and identity' standard is met." *Id*. at * 4 (citing *Grubbs*, 565 F.3d at 190-91).

To allege the particulars of a scheme to offer kickbacks, relators "must sketch how it was that Defendant provided remuneration to its clients, the form of that remuneration, how and why Defendant believed that remuneration would include new business, and how Defendant benefitted [sic] from the remuneration." *Ruscher*, 2014 WL 2618158, at *10. In keeping with Rule 9(b), relators must "allege the timeframe in which the scheme took place and which components of the Defendant organization were involved, even if [they] cannot allege the exact dates on which kickbacks were provided and the names of each individual with [the defendant entity] who authorized a kickback." *Id.* According to the court in *Ruscher*, even where courts have adhered to a relaxed Rule 9(b) standard, they have not "budged from the basic rule that the complaint must include a 'sufficient factual basis for [Plaintiff/Relator's] belief.'" *Id*. at * 11 (quoting *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 822 (E.D. Tex. 2008)). The court

stated this can take the form of a "representative sample" of the alleged wrongdoing. *Ruscher*, 2014 WL 2618158, at *11 (citing *United States ex rel. Bennett v. Boston Scientific Corp.,* No. CIV.A. H-07-2467, 2011 WL 1231577, at * 17 (S.D. Tex. Mar. 31, 2011); *King*, 232 F. Supp. 2d at 572 (finding that, even under a relaxed pleading standard, relators failed to plead fraud with particularity because they did not identify a single person involved in the alleged fraud, did not point to specific fraudulent claims, and did not specify a single date on which fraudulent activity occurred).

Finally, the Court notes that when the facts relating to the alleged fraud are "peculiarly within the perpetrator's knowledge," the pleading requirements of Rule 9(b) may be relaxed to allow the plaintiff to plead on information and belief, provided the complaint sets forth a factual basis for such belief. *Vavra,* 903 F. Supp. 2d at 484-85 (quoting *Thompson*, 125 F.3d at 903). This exception, however, should not "be mistaken for license to base claims of fraud on speculation and conclusory allegations." *Id.*

B. Defendants' assertions

Defendants assert Relators have alleged only general, nationwide schemes without any specifics regarding actual support services and how those services purportedly provide substantial, illegal value to physicians. Defendants assert Relators' investigation was a superficial one, and the FAC provides no details concerning the knowledge of Relator Health Choice Group. Rather, the investigatory effort involved alleged interviews with a handful of former employees; of the seven confidential interviewees referenced in the FAC, four worked for Lash, two for Bayer, one for Amerisource, and none for Amgen or Onyx. (FAC, ¶ 87). Relator Green worked for nonparty Ashfield. *Id*. at ¶ 27. Thus, according to Defendants, the FAC is lacking in details regarding the who, what, when, where, and how of Defendants' alleged kickback schemes.

Defendants further contend Relators have failed to allege with particularity the submission of a single actual false claim, or to link any such false claim(s) to the alleged kickback schemes. According to Defendants, this lack of detail also results in a failure to plead the essential FCA element of causation with the required particularity.

Additionally, Defendants assert Relators fail to sufficiently distinguish between the alleged acts of each defendant. As one example, Defendants point out that Amgen and Onyx were involved only in one of the medicines at issue—Nexavar; yet, according to Defendants, the FAC repeatedly makes undifferentiated allegations about all Defendants with respect to all three medicines at issue. Defendants assert the FAC similarly fails to explain which defendant undertook what alleged act, when those acts occurred and with whom, and—of particular importance—how those alleged acts caused a false claim that was submitted to the Government.

The Court first considers whether the FAC's kickback schemes are sufficiently supported by specific facts as required by Rule 9(b).

C. Whether the FAC's kickback schemes are sufficiently supported by specific facts as to each defendant

1. Relators' assertions

Relators assert they have sufficiently alleged three schemes to defraud the government, the timeframe, those involved, the mechanics, and an explanation of how the claims were false; thus, the time, place, contents, and identity standard is met. Relators further assert the FAC explicitly describes the role each defendant played in the "larger, jointly-executed scheme to violate the FCA." (Docket Entry # 52 at pg. 32). Relators argue each defendant is able to understand the nature of Relators' claims against it, and Relators have accordingly satisfied both the goal and standard of

Rule 9(b). *Id.* at pg. 33. Defendants disagree and point out the following details allegedly missing in the three schemes.

2. Details allegedly missing in the free nurse and reimbursement support services schemes (theories one and three)

The who

According to Defendants, Relators have provided inadequate detail regarding physicians who actually utilized free nurse or reimbursement support services or who were influenced to prescribe the medicines by the availability of those services. In response, Relators point out they have alleged fifteen examples of anonymous doctors ("Prescribers" 1-15) who were targeted with the free nurse or reimbursement support services program. Some representative examples include the following:

- Prescriber 1, a doctor located in Golden Valley, Minnesota. Prescriber 1 was among the 1,000 highest prescribers of Betaseron to Medicare patients in 2014 and 2015. Prescriber 1 had patients educated by the nurse educators and utilized the Support Services provided by Defendants. CI-2 was first introduced to Prescriber 1 in 2007. CI-2 educated Betaseron patients until 2015, including patients of Prescriber 1.

- Prescriber 8, a doctor located in Paterson, New Jersey. Prescriber 8 was among the1,000 highest prescribers of Nexavar to Medicare patients in 2014 and 2015. Prescriber 8 had patients educated by the nurse educators and utilized the Support Services. CI-5 educated Nexavar patients in 2014 and 2015, including patients of Prescriber 8.

- Prescriber 9, a doctor located in Teaneck, New Jersey. Prescriber 9 was among the 1,000 highest prescribers of Nexavar to Medicare patients in 2015. Prescriber 9 had patients educated by the nurse educators and utilized the Support Services. CI-5 educated Nexavar patients in 2014 and 2015, including patients of Prescriber 9.

- Prescriber 10, a doctor located in Montclair, New Jersey. Prescriber 10 was among the 1,000 highest prescribers of Nexavar to Medicare patients in 2014. Prescriber 10 had patients educated by the nurse educators and utilized the Support Services. CI-5 educated Nexavar patients in 2014 and 2015, including patients of Prescriber 10.

(FAC, ¶ 189).

According to Defendants, only four of the fifteen Prescribers listed in the FAC (Prescribers 1, 8-10) are alleged to have "utilized the Support Services" at all, without any mention of when they sought reimbursement, for which patients, or for what amounts. *Id*. As to those four Prescribers, the only individuals mentioned are CI-2 or CI-5 and the Prescribers themselves. *Id*. Defendants assert CI-2 and CI-5 are nurse educators, not reimbursement support representatives. *Id*. at ¶ 87. According to Defendants, by Relators' own account, "support staff," not prescribers, typically perform the administrative function to which the reimbursement services are relevant. *Id*. at ¶ 155. Thus, Defendants argue the FAC, including ¶189 (which includes only prescribers), does not identify *any* individuals who were involved in the scheme 3.

The what and the how

In what could be characterized as a challenge to the "what" and the "how" of Relators' allegations, Defendants assert Relators offer no detail to substantiate the conclusory allegations that these support services provide "a tangible benefit," "freed up time to see other patients," and "increased profitability." (FAC, ¶¶ 106-07). Defendants maintain Relators do not identify a single doctor who eliminated staff positions (or who such staff are) or otherwise received "substantial value" as a result of the free nurse or reimbursement support services provided for the three medicines at issue.

The when

Defendants argue the FAC lacks specificity as to the timeframe for Relators' claims. According to Defendants, Relators do not provide dates, approximate or otherwise, during which the Adempas patient support program, AIM, was in operation. (FAC, ¶ 95). They explain that one of the

nurse educator programs, Beta Plus, "has been around for at least the last decade" before ending in 2015, and another, Nex Connect, "began at least as far back as 2009" and is still in operation. *Id*. Defendants argue this level of specificity as to timing is inadequate under Rule 9.

The where

In the FAC, Relators list fifteen Prescribers and the city and state in which they practiced. The Prescribers are located exclusively in Minnesota and New Jersey, despite Relators' allegation that the "programs were/are available to patients across the United States." (FAC ¶¶ 95, 189). Relators also allege the territories of the confidential interviewees (including parts of Virginia, North Carolina, South Carolina, Minnesota, New York, New Jersey, Illinois, and Texas). *Id.* ¶ 87. However, Defendants argue the fact Relators identify the "assigned marketing region" of each interviewee is insufficient to meet Rule 9(b)'s "where" requirement.

3. Details allegedly missing in the white coat marketing by nurse educators (theory two)

Relators allege that "[s]ince at least 2006," defendants "have relied on nurse educators to help promote the Covered Products, obtain better access to Prescribers, and influence Prescribers to prescribe the Covered Products." (FAC, ¶ 108). According to Defendants, Relators claim "training was a vital component" of the scheme, *id*. at ¶ 117, and "[o]nce trained, nurse educators immediately began to gain access and infiltrate Prescriber offices and facilities." *Id*. ¶ 125. Defendants assert Relators allege nothing about who trained the nurse educators; when such training took place; what facilities the nurse educators "infiltrate[d];" where, other than "across the [entire] nation" these efforts occurred; or when, other than sometime over the past twelve years, any of this took place. Nor do Relators even generally allege any doctors or patients who may have been influenced by the so-called "white coat marketing" scheme such that a claim may have been caused to be submitted.

4. Discussion

What must be alleged to satisfy the standards of Rule 9(b)

Despite these alleged deficiencies, Relators argue there is more than sufficient information in the FAC to provide Defendants with fair notice of the charges against them. Relators focus on the relaxed standard in the Fifth Circuit following *Grubbs* and argue they can satisfy Rule 9(b) without pleading the above details.

In their reply, Defendants point out the Fifth Circuit, following *Grubbs*, has reiterated a relator must, at a minimum, plead the "who, what, when, where, and how" of the alleged fraud. *See United States ex rel. Stephenson v. Archer W. Contractors, L.L.C.*, 548 Fed. Appx. 135, 139 (5th Cir. 2013) (noting Rule 9(b) requires that a plaintiff set forth the who, what, when, where, and how of the alleged fraud and noting that even if the relator were able to allege in part the particularity which the Rule requires, she had not alleged the "identity of the person making the misrepresentation and what that person obtained thereby"); *see also United States ex rel. Colquitt v. Abbott Laboratories*, 858 F.3d 365, (5th Cir. 2017) (stating at a minimum a plaintiff must plead the "who, what, when, where, and how" of the alleged fraud).

The relator in *Colquitt* was a salesman for Guidant Corporation. *Id.* at 369. "Colquitt helped Guidant and later Abbott sell biliary stents for off-label use to doctors performing vascular procedures, and they taught him the tricks of the trade." *Id*. at 370. Colquitt filed a *qui tam* suit against Abbott, alleging Abbott and Guidant violated the FCA in three ways. The district court granted Abbott's motion to dismiss the anti-kickback allegations on the ground that Colquitt had failed to satisfy the heightened pleading requirements for fraud claims. *Id*. at 371.

In dismissing the kickback allegations, the district court found Colquitt had not described "any details of the actual claims made by the physicians or hospitals that allegedly received kickbacks." *Id*. "It found that although Colquitt had identified some specific hospitals and doctors that allegedly received kickbacks, he did not plead that any of these hospitals or doctors signed up to be Medicare providers or submitted certified claims for reimbursement for procedures using Abbott's stents." *Id.* According to the Fifth Circuit, this may have been too rigid an application of Rule 9(b), noting that if a relator cannot allege the details of an actually submitted false claim, the complaint "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 372. The Fifth Circuit held a strong inference that the named hospitals submitted claims to Medicare for vascular procedures using biliary stents could likely be drawn from Colquitt's allegations. *Id.*

However, the Fifth Circuit held Colquitt's allegations failed at the first part of the *Grubbs* standard. *Id.* Specifically, the complaint did "not allege the details of the scheme with sufficient particularity." *Id*. The Fifth Circuit explained as follows:

> It devotes a single, vague paragraph to the alleged kickback scheme, mentioning defendants' programs that provide 'significant volume discounts and rebates to hospitals that could not be attained based solely on biliary use, but required substantial vascular use of the stents in order to receive the discount or rebate.' That, along with reference to 'vascular specialists' who received dinners, training, and fellowships, is the extent of the details alleged about the scheme. No specifics about the discounts and rebates are provided. We are not told that a particular hospital (including the only two that are identified in the complaint, Valley Hospital Medical Center and Shady Grove Adventist Hospital) ever achieved these unspecified thresholds through off-label use of the stents. No particulars are alleged to show that the unidentified doctors who received the ill-defined benefits caused the hospital to use Abbott stents. In short, the complaint never links the alleged carrots to the purchase and use of the stents at either of the hospitals. Unlike details about the Medicare claims that ended up being submitted, much of this information would be

> known to a relator with original information about an unlawful kickback scheme. Rule 9(b) was not satisfied.

Id.

United States ex rel. Nunnally v. West Calcasieu Cameron Hosp., 519 Fed. Appx. 890 (5th Cir. 2013) is also instructive. In that case, Nunnally argued the Fifth Circuit's decision in *Grubbs* absolved *qui tam* relators of the heightened pleading requirements under Rule 9(b) and in the FCA itself. *Id*. at 893. The Fifth Circuit stated as follows:

> To the contrary, *Grubbs* reaffirms the importance of Rule 9(b) in FCA claims, while explaining that a relator may demonstrate a strong inference of fraud without necessitating that the relator detail the particular bill. *See* 565 F.3d at 190. We established that a relator could, in some circumstances, satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond mere possibility, without necessarily providing details as to *each* false claim. *Id.* This standard nonetheless requires the relator to provide other reliable indications of fraud and to plead a level of detail that demonstrates that an alleged scheme likely resulted in bills submitted for government payment. *Id.* Significantly, the complaint in *Grubbs* rested on the relator's actual description of a solicitation by two of the defendants to the relator to participate in an elaborate scheme to defraud the government, the particulars of which were there alleged.

Id. (emphasis in original).

Unlike the complaint in *Grubbs*, Nunnally's complaint merely offered sweeping and conclusory allegations of "verbal agreements" between the defendant and "various physicians," "without a shred of detail or particularity." *Id*. at 894. According to the Fifth Circuit, there was no information on the contents of those agreements, the identity of any physicians, actual inducements, or improper referrals. *Id*. The complaint did not specify who in particular was involved in the one cited example of an "agreement," or how it constituted an illegal kickback. *Id.*

To the extent Nunnally brought separate claims under the FCA premised on presenting false claims, or making false records, separate from the alleged AKS violation, the Fifth Circuit again held

Nunnally had failed to plead with the requisite particularity as required by *Grubbs. Id*. at 895. Specifically, the court concluded as follows:

> Nunnally's wholly generalized allegations of false claims presented to the Government do not 'alleg[e] *particular* details of a scheme' (emphasis added) and are not 'paired with reliable indicia that lead to a strong inference that [false] claims were actually submitted.' *See Grubbs,* 565 F.3d at 190. We held in *Grubbs* that the contents of a false claim need not always be presented under this subsection because, given that the Government need not rely on or be damaged by the false claim, 'the contents of the bill are less significant.' *Id.* at 189. This does not absolve Nunnally of the burden of otherwise sufficiently pleading the time, place, or identity details of the traditional standard, in order to effectuate Rule 9(b)'s function of fair notice and protection from frivolous suits. *See id.* at 190. Nunnally's allegations of a scheme to submit fraudulent claims are entirely conclusory, do not offer factual information with sufficient indicia of reliability, and do not demonstrate a strong inference that the claims were presented to the Government in violation of § 3729(a)(1).
>
> Further, § 3729(a)(2) "'requires [ ] that a defendant made a false record or statement for the purpose of getting a false or fraudulent claim paid by the Government.' *Id.* at 192. '[T]he recording of a false record, when it is made with the requisite intent, is enough to satisfy the statute.' *Id.* In *Grubbs,* the relator alleged several specific incidents where doctors admitted to 'writ[ing] notes' concerning physician visits that did not actually take place. *Id.* Nunnally's complaint does not contain any detail of comparable particularity. He merely alleges there was 'written and/or implied certification to the Medicare program that it was in compliance with all of the Medicare's program rules.' He points to no specific instance of such a record or statement. As Nunnally has not met his burden under Rule 9(b), his claim was properly dismissed.

Id.

In sum, the Fifth Circuit requires relators to "specify the statements intended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Paramedics Plus*, 2017 WL 4812443, at *3 (citations omitted). Therefore, the complaint should, at a minimum, set forth "the who, what, when, where, and how of the alleged fraud." *Id.* (quoting *Stephenson*, 548 Fed. Appx. at 139 (citing *Thompson*, 125 F.3d at 903). That said, in the context of the FCA, the"who, what, when, where, and how" of the alleged fraud is "not

a straitjacket for Rule 9(b)." *Vavra*, 903 F.Supp.2d at 484 (citing *Grubbs*, 565 F.3d at 190). "Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act." *Grubbs*, 565 F.3d at 190.

The Court now considers whether Relators have sufficiently pleaded the time, place, and identity details of the traditional standard in order to effectuate Rule 9(b)'s function of fair notice. *Nunnally*, 519 Fed. Appx. at 895.

The "what" and the "how"

In *United States ex rel. Forney v. Medtronic, Inc.*, discussed above, the relator alleged the defendant paid healthcare providers illegal kickbacks in the form of free services and staff to induce providers to choose the defendant's products over those of its competitors. 2017 WL 2653568, at *1. The court held the relator failed to plead the details of the alleged kickback scheme with sufficient particularity and granted the motion to dismiss without prejudice. *Id.*

The relator alleged the defendant engaged in a nationwide marketing scheme for devices such as pacemakers and defibrillators in which the defendant directed employees to gather extensive data about hospital and physician practices and to create direct relationships with patients; the defendant aimed its marketing at physicians and others who had the ability to impact purchasing decisions. *Id.* "A central part of [the defendant's] marketing strategy was to provide free services to its customers," such as free surgical support, implant device follow-up that it continued to offer long after device implantation, and free staff at clinics at which the defendant's employees would spend four to eight hours conducting interrogations and other services. *Id.* According to the relator, by offering such free services, the defendant induced physicians and others with purchasing power to select the defendant's devices because "the free labor benefitted [the physicians'] bottom line." *Id.* In the

amended complaint, the relator "provided a snapshot of the frequency with which [the defendant] provided the free services in various Pennsylvania locations, although the pattern allegedly prevailed across the nation." *Id*. at *2.

The relator further alleged the defendant offered free assistance on billing its devices to federal health care programs. *Id.* The defendant also allegedly briefed and updated the defendant's customers on how to receive maximum reimbursement from the government, thus causing "providers to submit false claims for payment to fiscal intermediaries because physicians and hospitals received staffing kickbacks from [the defendant], submitted claims for payment, and falsely certified that they had complied with the anti-kickback laws and regulations." *Id*.

The court first held the relator had sufficiently alleged the defendant's free services induced physicians to choose the defendant's products, thus sufficiently alleging the third requirement of a prima facie case under the AKS: that one purpose of the free services was to induce future purchases. *Id*. at *4. However, the court found the federal FCA claim deficient in other respects. Specifically, the relator failed to allege with particularity how the free services constituted illegal remuneration under the AKS.[13] *Id*.

The court relied on the part of the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers regarding "Relationships with Purchasers and their Agents," wherein the OIG indicates product support services that are specifically tied to the support of the purchased product," standing alone, do not implicate the AKS; rather, such services may constitute illegal remuneration if those services provide some "substantial independent value to the purchaser." 68

[13] The court also found the relator failed to allege the defendant acted "knowingly and willfully" as required by the AKS and failed to connect the alleged kickbacks to resulting false claims with sufficient particularity. *Forney*, 2017 WL 2653568, at *5.

Fed. Reg. 23731-01, 2003 WL 2010428, at *23735. According to the court, the amended complaint alleged the free services benefitted physician practices and the free labor benefitted the physicians' bottom line, but the relator failed to allege with the particularity Rule 9(b) requires that the free services saved the providers money. *Forney*, 2017 WL 2653568, at *4. "For example, [the relator] ha[d] not specified which of the services that Medtronic provided in exchange for purchasing Medtronic products would not have had to have been otherwise performed by the physician or the physician's staff. All that [the relator had] alleged with particularity about the free services themselves is that Medtronic provided technical product support in connection with the purchase of its products." *Id.*

The court held offering "well-supported products might induce physicians to purchase Medtronic products, but only because they are better-supported products than competing products." *Id.* However, the court noted simply stating the services generally benefitted the defendant's customers' bottom lines or that the physicians used Medtronic's services in lieu of having to pay their own employees was not sufficiently specific to meet the pleading requirements of Rule 9(b) without alleging *how* those services substantially benefitted the customers' bottom lines. *Id.* (emphasis in original). The court noted that if the relator filed a second amended complaint, "she must describe with sufficient specificity how Medtronic's free services crossed the line separating permissible product support from illegal remuneration with independent value to the purchaser" and also "demonstrate that any independent value to the purchaser was *substantial*." *Id*. (emphasis in original).

In its analysis on Defendants' Rule 12(b)(6) arguments on what constitutes remuneration, the Court previously found herein Relators have alleged how the free nurse and reimbursement support

services could have substantial independent value to the Prescribers. Relators' 100-page FAC describes the nature of the free nurse and reimbursement support services schemes. As discussed above, the FAC contains plausible allegations describing: Defendants' motives (¶¶ 14, 94, 99); the development and administration of the nurse education program by Bayer, Amgen, and Amerisource ((Scheme 1) ¶¶ 92-95); the scope of the Free Nurse program and the benefits the program confers on Prescribers and their staff, which induce them to prescribe the Covered Products (¶¶ 97-107); the development of the Support Services program by Bayer, Amgen, and Amerisource ((Scheme 3) ¶¶ 146-150); an explanation of how the Support Services program functions and how it provides benefits to Prescribers and their staff that induce them to prescribe Bayer and Amgen products (¶¶ 151-167); the Government Programs that reimburse prescriptions for the Covered Products (¶¶ 43-86); an explanation of why claims submitted to the Government programs for the Covered Products are false claims (¶¶ 3-15, 29-38, 47-57, 67, 68, 80, 85, 188, 190-204); and an explanation of why Defendants knew these false claims would be submitted (¶¶ 85, 161, 184-204).

The FAC also alleges the manner in which nurses that participate in the White Coat Marketing program are trained, expected to and ultimately do in fact promote the Bayer and Amgen products (scheme 2). (FAC, ¶¶ 108-144). According to the FAC, Bayer and Amgen contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to appear to be independent. *Id*. ¶ 115. Bayer, Amgen, Amerisource, Lash, and non-party Ashfield designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to Prescribers. *Id*. Although the nurses were independent contractors and were purportedly "educators," they were expected to and did recommend the Covered Products. *Id.* ¶ 116.

Despite these allegations, Defendants persuasively argue in the Rule 9(b) context that support services and education services tailored to patients taking a specific medication would not necessarily allow doctors to eliminate entire administrative positions or increase patient visits. Relators do not identify a single doctor who eliminated staff positions (or who such staff are) or otherwise actually received "substantial value" as a result of the free nurse or reimbursement support services provided for the three medicines at issue. The Court further notes none of the above allegations specifically reference Onyx, and Lash is only referenced in the allegations regarding the white coat marketing by nurse educators scheme.

Although Relators' allegations, and the inferences drawn from those allegations, are sufficient to satisfy Rule 12(b)(6), the Court is not convinced the detail regarding the "what" and the "how" satisfies Relators' Rule 9(b) obligations, especially considering the FAC does not sufficiently distinguish between the alleged acts of each defendant in many instances. Allegations that lump all defendants together and fail to segregate the alleged wrongdoing of one from those of another do not satisfy rule 9(b). *See In re Urcarco Securities Litigation*, 148 F.R.D. 561, 569 (N.D. Tex. 1993), *aff'd*, 27 F.3d 1097 (5th Cir. 1994). The FAC fails to explain which defendant undertook what alleged act, when those acts occurred and with whom, and—as discussed below—how those alleged acts caused a false claim that was submitted to the Government. The FAC contains few allegations against Onyx separately. And, as pointed out by Relators, Onyx and Amgen were involved only in one of the medicines at issue, but the FAC repeatedly makes undifferentiated allegations about all defendants with respect to all three medicines at issue.[14]

[14] By contrast, in *United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *9 (N.D. Tex. Sept. 30, 2016), the court held the relator did not lump Altegra's alleged misconduct together with misconduct by Censeo and other third-party coding vendors. The complaint in that case distinguished between the two entities and described the parties'

The "when"

Relators also fail to sufficiently identify when the alleged schemes to violate the AKS took place. As noted above, Defendants assert Relators do not provide dates, approximate or otherwise, during which the Adempas patient support program, AIM, was in operation. (FAC, ¶ 95). Defendants further assert Relators' timeframe allegations regarding the nurse educator programs Beta Plus ("has been around for at least the last decade" before ending in 2015) and Nex Connect ("began at least as far back as 2009" and is still in operation) are insufficient. *Id*.

Relators focus on the expansive and long-lasting timeframe of the schemes (which encompass every Prescriber who has received free nurse or reimbursement support services paid for by Bayer and Amgen or who received a visit from a nurse educator concerning MS, cancer, and pulmonary hypertension on behalf of Bayer and Amgen since at least 2006 (FAC, ¶¶ 184-186)). According to Relators, in cases where the relator is alleging the fraud occurred over a period of years, less specificity is required to satisfy the pleading requirements of Rule 9(b). *See United States ex rel. Lee v. SmithKline Beecham, Inc.,* 245 F.3d 1048, 1051 (9th Cir. 2001) ("While a complaint that covers a multi-year period may not be required by Rule 9(b) to contain a detailed allegation of all facts supporting each and every instance of submission of a false claim, some information on the false claims must be included.").

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relationship with each other and to the scheme. The relator alleged "Censeo created its assessment form, developed the allegedly improper coding practices, and instructed Altegra on how to follow its practices, playing the role of leader in the scheme, and Altegra was a follower, that reluctantly, but knowingly, implemented Censeo's improper coding practices." *Id.*

Where these circumstances exist, courts have permitted the relator to plead fraud based on information and belief. Here, the fraud alleged by Relators consists of schemes that occurred over the course of several years and involved numerous acts. Given these facts, the Court will relax the Rule 9(b) pleading requirement. Even under the relaxed standard, Relators must set forth a sufficient basis for their belief. *Foster*, 587 F. Supp. 2d at 822.

Relators allege CI-1 was employed by Lash as a nurse educator from 2007 until March 2014; CI-2 was employed by Americource as a nurse educator from 2002 until October 2015; CI-3 was a drug rep for Bayer from December 2012 until July of 2014; CI-4 was employed by Lash as a reimbursement support services representative for Betaseron from October 2012 until March 2015; CI-5 was employed by Lash as a nurse educator for Nexavar from 2013 until 2015; CI-6 was employed by Bayer as a Nexavar drug rep from 2005 until 2013; CI-7 was employed by Lash as a reimbursement support services representative from September 2013 until February 2014; and Relator Green was employed by non-party Ashfield as a nurse educator for Adempas from November 2015 through April 2017. (FAC, ¶ 87).

In *Ruscher*, the court denied dismissal of a complaint specifically alleging that a pharmaceutical company forgave certain debts from its nursing-facility customers in order to induce referrals of other, more profitable patients. 2014 WL 2618158, at *3–4. The defendants argued the relator did not allege when anyone within Omnicare authorized the kickbacks, when the alleged scheme began, or when any account balances were forgiven. *Id.* at * 15. The court noted the relator had worked at Omnicare from July 2005 until August 2008 and had referenced e-mails discussing past-due bills sent in 2006 as well as balances due between January and September 2008. *Id.* The

court was therefore convinced the relator had satisfied Rule 9(b)'s particularity allegations of kickbacks that took place between 2005 and 2008. *Id*. at * 16.

However, according to the court, the "leap from that three-year period to 1998 and the present [was] remarkable, and ultimately unsupportable." *Id*. (internal quotations omitted). The court granted the motion to dismiss as to claims arising out of kickbacks paid before January 1, 2005 and after December 31, 2008. *Id*. at *17 (finding the relator had pleaded with particularity AKS violations that took place between 2005 and 2008).

In *Woodard*, Judge Crone granted in part the defendant's motion to dismiss for failure to satisfy the pleading requirements of Rule 9(b) and dismissed the relator's overfill and kickback claims without prejudice on the basis of pleading deficiencies. 2011 WL 13196556, at *1. The relator later filed a Fourth Amended Complaint reasserting the overfill and kickback claims. *Id*. at *2. The defendant then sought dismissal of the overfill and kickback claims with prejudice, arguing the repleaded claims still lacked the factual specificity required by Rule 9(b). *Id*. The court granted the motion in part, finding the relator failed to plead with specificity the portions of his kickback claim that relied on the receipt of education seminars and educational grants. However, the court denied the remaining grounds for dismissal, declining to dismiss the overfill claim. *Id*. at * 8, 12.

Notably, the relator identified "specific facilities where he personally counseled DaVita employees on the financial benefits of the overfill billing, specific time frames in which these meetings occurred and specific DaVita employees–identified by title–with whom he conferred." *Id*. at * 4. The court found this sufficient to satisfy Rule 9(b)'s requirements. *Id*.

These types of allegations are missing in the FAC, as further explained below. Similar to the court in *Foster*, discussed later herein, the Court finds, in spite of the leniency, the FAC is still

deficient because it fails to plead sufficient facts to support Relators' allegations made on information and belief. *Foster*, 587 F. Supp. 2d at 822; *see also United States ex rel. Lam v. Tenet Healthcare Corp*., 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006) (finding the relators' allegations that the fraudulent events took place at some point in the 1980s, between 1995 and 2002, and in 1999 insufficient to plead the "when" with specificity and noting that even if the court were to relax the pleading standards, the relators would still need to allege at least approximate dates of the alleged fraud in a manner such that they appear to be more than mere speculation or conclusory allegations).

The "who" and "where"

Regarding the "who," the FAC identifies fifteen confidential Prescribers as some examples of prescribers who received the free nurse education services or support services offered by Defendants in part to induce a recommendation of the Covered Products. As noted above, the FAC also contains information from seven confidential interviewees and Relator Green. Of the seven confidential interviewees referenced in the FAC, four worked for Lash, two for Bayer, and one for Amerisource. (FAC, ¶ 87). None of the CIs worked for Amgen or Onyx. Relator Green worked for non-party Ashfield. *Id*. at ¶¶ 27, 87.

The "who" may be viewed differently in the context of a company-wide scheme. *See Ruscher*, 2014 WL 2618158, at * 14 ("It is only natural that it will be harder to point to specific individuals when discussing a kickback scheme that (allegedly) became, in essence, a part of the corporate culture."). However, a review of the cases reveals more detail is required than that provided in the FAC. In *Ruscher*, the court noted the somewhat relaxed pleading standard that applied to allegations of "long-running fraud" and then held the relator had pleaded enough "who"

to survive the motion to dismiss. *Id*. at *12. Importantly, the relator had identified Omnicare CEO Joel Gemunder and others on his senior management team as part of the "who." *Id*. at *13.

In *United States ex rel. Cestra v. Cephalon, Inc*., No. 14-1842, 2015 WL 3498761, at *4 (E.D. Penn. June 3, 2015), cited by Relators regarding what is required to adequately plead causation, the relator identified the "who" of specific departments and individuals that participated in creating and furthering the off-label promotion scheme and the specific doctors and organizations that participated in the various methods of off-label promotion such as speaker programs or continuing medical education. The relator identified promotional speakers by name, practice, and number of speaking engagements and compensation and pleaded the "when" and "where" of the scheme by alleging the specific meetings and conversations in which off-label promotion occurred. *Id*. Thus, the court held the relator had pled with particularity the details of a scheme to submit false claims to the government for reimbursement and then considered whether the relator had paired those particular details with "reliable indicia that lead to a strong inference that claims were actually submitted." *Id*. at *5 (quoting *Foglia*, 754 F.3d at 157-58).

In *Grubbs*, the relator had first-hand knowledge of the fraudulent billing scheme. As the Fifth Circuit explained in *Grubbs:*

> The complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud. Grubbs describes in detail, including the date, place, and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot. He alleges his first-hand experience of the scheme unfolding as it related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred. Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill.

Id. at 191–92. Dr. Grubb's first-hand experience at the dinner, combined with the "complaint's list of dates that specified, unprovided services were recorded," were enough to satisfy the pleading requirements of Rule 9(b). *Id.* at 192. Unlike the claims against the doctors, who allegedly invited Dr. Grubbs to commit fraud, the complaint in *Grubbs* did not sufficiently allege the hospital itself acted with the requisite intent. *Id.*

Defendants argue Relators have not alleged the type of information the *Grubbs* relator did. The Court agrees. As pointed out by Defendants, ¶ 189 of the FAC, which purports to be a list of Prescribers "who received the free nurse education services or Support Services," makes no specific mention of the white coat marketing by nurse educators scheme. For nine of these fifteen doctors (Prescribers 4-7 and 11-15), Relators do not even allege that the office or its patients were educated by the nurse educators (free nurse services scheme). *Id*. ¶ 189.

Even as to the six Prescribers whose patients allegedly received free nurse education services (Prescribers 1-3 and 8-10), Relators offer no details regarding (1) who was involved (not a single staffer, patient, or anyone other than, by implication, the anonymous interviewee him- or herself); (2) where the nurse education occurred (other than Relators' general allegation that Bayer and Amgen's nurse educator patient trainings were usually in the patients' homes, *see id*. at ¶ 96); or (3) when (beyond the general assertion that "CI-2 educated Betaseron patients until 2015" and "CI-5 educated Nexavar patients in 2014 and 2015," *id*. at ¶ 189). *See Woodard*, 2011 WL 13196556, at *12. ("Rule 9(b) simply does not allow [relator] to rest his pleading of a years-long scheme . . . on two allegations, each of which is itself significantly lacking in supporting facts.").

Only four doctors (Prescribers 1, 8-10) are alleged to have "utilized the Support Services," and for those four, there is no mention of when they sought reimbursement, for which patients, for

how may patients, or for what amounts. *Id*. As to those four Prescribers, the only individuals mentioned are CI-2 or CI-5 and the Prescribers themselves. *Id*. CI-2 and CI-5 are nurse educators, not reimbursement support representatives. *Id*. ¶ 87. By Relators' own account, "support staff," not prescribers, typically perform the administrative function to which the reimbursement services are relevant. *Id*. ¶ 155. Thus, as Defendants argue, the FAC, including ¶189 (which includes only prescribers), does not identify any individuals who were involved in the reimbursement support services scheme (scheme 3).[15]

The "where"

Regarding the alleged nationwide scope of the schemes, the FAC alleges as follows:

> Defendants employed the three schemes detailed above across the nation, and the Covered Products were marketed, prescribed, and sold nationwide. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for each of the Covered Products. By way of some examples, approximate Medicare claim data concerning the Covered Products for certain years is summarized in the paragraphs below.

(FAC, ¶ 190). However, the Prescribers specifically referenced in the FAC are located exclusively in Minnesota and New Jersey. (FAC ¶¶ 95, 189).

In *United States ex rel. Texas v. Planned Parenthood Gulf Coast*, No. 9-09-CV-124, 2012 WL 13036270, at *6 (E.D. Tex. Aug. 10, 2012), the defendant argued that because the relator failed to plead representative examples of patient records which were allegedly altered and facts to support the conclusion that the allegedly false claims were *actually submitted* by the defendant to the state and federal governments for payment, the third amended complaint did not meet Rule 9(b)'s heightened pleading requirement. According to the court, the third amended complaint alleged the

[15] In any event, it is unclear how these doctors, their staffs, or their patients fit into the alleged schemes.

defendant violated the FCA and the Texas Medical Fraud Prevention Act by charging patients for services not actually provided, providing medically unnecessary services, and falsifying documentation material to the payment of those claims. *Id.* The relator alleged the defendant's employees would bill federal and state government programs based on a predetermined list of services regardless of whether the patient's chart indicated the services were actually provided and, even if provided, were not medically necessary. *Id*. The court concluded the facts pled in the third amended complaint stated a plausible claim for relief and had been pled with sufficient particularity to satisfy Rule 9(b). *Id.* at *5. Specifically, the court stated:

> Although the Complaint does not conclusively show that the claims were actually submitted for payment, the facts as alleged provide the court with a reliable indicia that lead to a strong inference that the claims were actually submitted. *Grubbs*, 565 F.3d at 190. The third amended complaint also provides that where a patient's chart did not contain documentation to support services marked on the bill, PPGC employees routinely altered the chart to match the bill. The court finds that the facts as pled create a plausible claim for relief under the presentment and false records provisions of the FCA and TMFPA.
>
> The complaint has been pled with sufficient particularity to satisfy Rule 9(b). Relator's third amended complaint contains the basic framework, procedures, and nature of defendant's alleged fraudulent scheme to maximize revenues along with specific examples in support of PPGC's alleged fraudulent conduct brought under the FCA and TMFPA. Exhibit 1 to Relator's third amended complaint specifically lists potential witnesses and their expected testimony in some detail. The third amended complaint apprises PPGC of 'who' allegedly committed the wrongful acts, 'what' is alleged, 'when' the wrongful acts occurred, 'where' the acts made the basis of the suit took place, or 'how' the alleged fraud occurred.
>
> PPGC allegedly submitted false claims and falsified records to Medicaid on a regular if not daily basis during Relator's entire period of employment—from October 1999 through February 2009. The acts allegedly occurred at all of PPGC's 12 clinics. The names of numerous PPGC employees and directors who allegedly participated in the fraud or were responsible for creating the alleged fraudulent policies are specifically listed in the third amended complaint. . . . The third amended complaint describes the specific process by which PPGC caused the submission of the false claims to the government and allegedly falsified records to conceal their fraud. Accordingly, at this stage, '[d]iscovery can be pointed and efficient, with a summary judgment following

> on the heels of the complaint if billing records discredit the complaint's particularized allegations.' *Grubbs*, 565 F.3d at 191.

Id. at * 6.

The allegations in the FAC here fall short of those in *Planned Parenthood* and are more akin to the deficiencies found in *United States ex rel. Woodard v. DaVita, Inc.*, No. 1:05-CV-227, 2010 WL 11531271, at *6 (E.D. Tex. Dec. 21, 2010). There, Judge Crone found Woodard generally alleged a scheme whereby the defendant received various products and services for free or at discounted rates, but his allegations were not supported by specific facts and failed to satisfy Rule 9(b). Unlike in the *Planned Parenthood* case, Woodard did not "identify any specific DaVita facility where the alleged scheme occurred nor any Amgen representative, except himself, who provided DaVita with EPO discounts or free training." *Id*. (citing *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 385 (5th Cir. 2003) (dismissing complaint where location of alleged fraud was not identified); *Patel v. Pacific Life Ins. Co.*, No. 3:08–CV–0249–B, 2009 WL 1456526, at *10 (N.D. Tex. May 22, 2009) (finding a complaint that did not connect alleged fraudulent statements to the time and place in which they were made deficient under Rule 9(b)); *United States ex rel. Richardson–Eagle, Inc. v. Marsh & McLennan Co., Inc.*, No. Civ. A. H–05–0411, 2005 WL 3591014, at *7 (S.D. Tex. Dec. 30, 2005) (dismissing claim under Rule 9(b) where complaint failed to allege where or when fraud took place); *United States v. Crescent City, E.M.S., Inc.*, 151 F.R.D. 288, 290–91 (E.D. La. 1993) (holding that, especially where plaintiff had access to the relevant information, a complaint that did not identify where the alleged fraud took place was not pleaded with sufficient particularity)).

Woodard argued the identification of his assigned marketing region, including the Texas cities of Livingston, Cleveland, Lufkin, Nacogdoches, Bryan, Kingwood, Humble, and Houston, was

sufficient to satisfy Rule 9(b)'s specificity requirement. *Id.* at *6, n.2. Woodard further argued his mention in the "Jurisdiction and Venue section of his Third Amended Complaint of the Livingston Dialysis Center," where he "consulted with DaVita personnel about [EPO] use," adequately identified the location where the alleged fraud took place. *Id.*

Judge Crone stated these arguments failed "because, within the Factual Background of Woodard's Third Amended Complaint, not a single specific site [was] identified where the alleged fraud occurred." *Id.* According to Judge Crone, "Woodard's mere mention of the Livingston Dialysis Center [was] insufficient to meet Rule 9(b)'s pleading requirement because Woodard [did] not allege the specific details of what occurred at the center. Rather, he mention[ed] the center only to satisfy the court's jurisdictional requirements." *Id.*

Likewise here the FAC does not identify a single, specific site where the alleged fraud occurred.

Conclusion

For all these reasons, the Court finds Relators have not met their burden of "sufficiently pleading the time, place, or identity details of the traditional standard, in order to effectuate Rule 9(b)'s function of fair notice and protection from frivolous suits." *Nunnally*, 519 Fed. Appx. at 895. As noted above, to plead FCA liability predicated on AKS violations in the Fifth Circuit, relators need to allege the particular details of a scheme to offer kickbacks in order to induce referrals, coupled with reliable indicia leading to a strong inference that claims based on such referrals were actually submitted to the government. *Ruscher*, 2014 WL 2618158, at *10. Even if the Court were to assume Relators had sufficiently alleged the particular details of the schemes, Relators would still

have to couple their allegations with reliable indicia of reliability demonstrating a strong inference false claims were submitted to the Government.

D. Whether the FAC pleads factual information with sufficient indicia of reliability demonstrating a strong inference false claims were submitted to the Government

1. Defendants' assertions

As a separate basis for dismissal under Rule 9(b), Defendants assert Relators have failed to plead facts about the actual submission of any false claims as a result of the alleged kickback schemes. According to Defendants, the FAC does not identify a single doctor, patient, or anyone else who submitted a false reimbursement claim, let alone the approximate date or amount of the claim. Despite Relators' attempt to provide information regarding a few Prescribers, Defendants argue the allegations do not tie any of the inadequately detailed support services to the actual submission of any reimbursement claim. *See United States ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 15 (1st Cir. 2016) (noting the relators had failed to tie their "independently unexceptional allegations" (that certain doctors, at various points, were enrolled in federal reimbursement programs, received services and incentives from the defendants, and prescribed Xolair) "together into particularized charges about specific fraudulent claims for payment").

For instance, regarding "Prescriber 1," who is representative of the remaining six Prescribers who allegedly received some type of support services, Relators state:

> Prescriber 1, a doctor located in Golden Valley, Minnesota. Prescriber 1 was among the 1,000 highest prescribers of Betaseron to Medicare patients in 2014 and 2015. Prescriber 1 had patients educated by the nurse educators and utilized the Support Services provided by Defendants. CI-2 was first introduced to Prescriber 1 in 2007. CI-2 educated Betaseron patients until 2015, including patients of Prescriber 1.

(FAC, ¶ 189). Regarding Relators' assertion that Prescriber 1 was at least the 1,000th highest prescriber of Betaseron for 2014-2015, Defendants argue this could mean Prescriber 1 had only a

few patients on the medicine. Regarding Relators' allegation that Prescriber 1 "had patients" educated by CI-2 and "utilized the Support Services," Defendants argue Relators do not allege any specific instance in which one of the medicines was prescribed as a result of either the free nurse or reimbursement support services programs. Nor do Relators make the necessary connection that a claim was then submitted through Government healthcare programs. *See King*, 871 F.3d at 332 ("[I]t would be speculation to infer that compensation for professional services legally rendered *actually caused* the physicians to prescribe [defendant's] drugs to Medicaid patients.") (emphasis added). According to Defendants, Relators similarly fail to establish a causal link between the submission of false claims and the conduct alleged in the second scheme (white coat marketing by nurse educators). Defendants contend Relators do not make the needed connection that false claims resulted from these practices.

2. Applicable law

It is not enough for Relators to "portray[] the scheme and then summarily conclude[]" that false claims were submitted. *See Bennett*, 747 F. Supp. 2d at 782 (dismissing FCA suit because the relator did not allege "the time or place of the allegedly false representations regarding [the drug], the nature or content of claims made which were allegedly fraudulent, or that doctors to whom Plaintiff promoted off-label use of [the drug] actually submitted false claims to the Government for off-label uses"); *see also United States ex rel. Doe v. Lincare Holdings, Inc.*, No. 5:15-CV-19-DCB-MTP, 2017 WL 752288, at *6 (S.D. Miss. Feb. 27, 2017) (dismissing FCA action as "lack[ing] the requisite indicia of the specific scheme to submit false claims" where the complaint "fails to identify any [] personnel who [participated in the scheme] or any billing personnel who submitted false claims as a result"). At the pleading stage in *Grubbs*, the complaint averred at least one overt act of

false billing – including date and physician – for each defendant who allegedly submitted false claims. *Wall*, 2016 WL 3449833, at *21 (citing *Grubbs*, 565 F.3d at 189-90).

In *Foster*, Judge Heartfield found, even under a relaxed standard, the relator had failed to set forth the factual basis for his "information and belief" that the kickback scheme resulted in the submission of false claims. 587 F. Supp. 2d at 825. With some degree of particularity, Foster had described various financial incentives paid by a pharmaceutical company (BMS) to a health maintenance organization (OHP) and its representatives. Foster alleged these kickbacks resulted in BMS' drugs being included in the OHP formulary and that such a placement caused "OHP Physicians" to prescribe BMS' drugs not only to OHP patients but also to physicians' entire patient population, comprised of, among others, Medicaid subscribers. *Id.* at 824.

However, Foster did not provide one "factual detail or example to support this allegation." *Id*. He did not name any OHP physicians who issued such prescriptions, nor any patient who received them – much less show the patient was connected to Medicaid. *Id*. Foster did not even provide general statistical information to indicate the frequency with which OHP doctors prescribed BMS drugs. *Id.* "The only factual details Foster supplie[d] in support of his AKS-based claims [were] his allegations that BMS provided kickbacks to OHP." *Id.* Judge Heartfield held Foster did not provide any factual details from which the court could reasonably infer a link between the kickback scheme and the submission of a claim for payment to the government. *Id.* at 824-25 (citing *United States ex rel. Rost v. Pfizer, Inc*., 507 F.3d 720, 733 (1st Cir. 2007), *overruled on other grounds by Allison Engine v. United States ex rel. Sanders*, 533 U.S. 662 (2008) (the pleadings may raise facts that "suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility.")).

The First Circuit in *Rost*, cited by Judge Heartfield, found the complaint "amply describe[d] illegal practices in which [the defendant] allegedly engaged" but "d[id] not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." 507 F.3d at 732–33. The *Rost* court stated it was possible the doctors who prescribed the drug off-label did not then seek federal reimbursement. *Id.* at 732.

Later, in another *qui tam* action alleging the defendant induced third parties to file false claims with the government, the First Circuit distinguished *Rost* and concluded that "Duxbury d[id] more than 'suggest fraud was possible.'" *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29–30 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010) (quoting *Rost,* 507 F.3d at 733). The court noted that in cases in which it is alleged the defendant induced third parties to file false claims with the government, as opposed to actions alleging the defendant made false claims to the government, a relator can satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility" without necessarily providing details as to each false claim. *Id.* at 29.

Unlike Rost, Duxbury identified eight hospitals that submitted false claims and, although he did not list specific claims, Duxbury provided "information as to the dates and amounts of the false claims *filed by these providers with the Medicare program.*" *Id.* at 30 (emphasis added). Duxbury provided more specifics with respect to other medical providers. For example, "[a]s to St. Joseph's Hospital, Duxbury allege[d] that the hospital submitted approximately 4,800 claims a month for Medicare reimbursement based upon OBP's unlawful kickbacks." *Id*. (internal quotations omitted). The court acknowledged it was "a close call" even under a "more flexible standard" of Rule 9(b), but it ultimately held Duxbury satisfied the Rule 9(b) requirement because he had "alleged the

submission of false claims across a large cross-section of providers that allege[d] the 'who, what, where and when of the allegedly false or fraudulent representation'" and "also alleged facts with respect to the medical providers he identifie[d] that support[ed] his claim that [the defendant] *intended* to cause submission of false claims." *Id.* (citation omitted) (emphasis added).

3. Discussion

Unlike the relator in *Duxbury,* Relators do not allege any information as to dates or amounts of any false claims for reimbursement to Medicare, Medicaid, or any other federal health care program. Similarly, the relator in *United States ex rel. Nowak v. Medtronic, Inc*., 806 F. Supp. 2d 310 (D. Mass. 2011), pointed to no such claims and instead relied entirely on a statistical probability: "if ninety percent of all biliary stents are used off-label, and eighty percent of medical device purchases are paid for by Medicare or Medicaid, then a significant portion of the health care providers who bought Medtronic's biliary stents both used those stents for off-label purposes and improperly submitted requests for reimbursement to federal agencies for that off-label use." *Id*. at 354. According to the relator in *Nowak*, in light of the extensive and detailed allegations regarding Medtronic's active off-label promotional activities, this met a "standard of plausibility—even probability—that at least *one* claim was submitted based on the misrepresentations." *Id.* (emphasis in original).

The court found the relator's reasoning omitted "an important step in the analysis in the *medical device* context." *Id.* (emphasis in original). According to the court, the use of the biliary stent off-label must not be "medically necessary" in light of the alleged misrepresentation of the stent's safety and efficacy in the vasculature, and identifying such a claim significantly reduced the relator's statistical probability and would require an individual claim-by-claim review of medical

necessity. *Id.* "Thus, with no specific claim alleged, identifying even one false or fraudulent claim may be akin to finding a needle in a haystack." *Id*. The court was not satisfied Nowak's pleading satisfied the "flexible, yet still meaningful, standard of particularity required by *Duxbury* and *Rost*." *Id*. at 354-55.

Nowak relied on several cases in which district courts had found Rule 9(b) compliance based upon a detailed alleged scheme of fraud but no—or few—specifically alleged claims. *Id*. at 355. One of the cases suggested impracticality can relax the requirements of Rule 9(b) when "facts underlying the fraud are peculiarly within the defendants' control" or "the alleged scheme of fraud may involve numerous transactions or transactions that occur over a long period of time, and pleading the specifics with regard to every instance of fraudulent conduct may be impractical." *Id.* (quoting *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.,* 147 F.Supp.2d 39, 47 (D. Mass. 2001)). The *Nowak* court noted the First Circuit has recognized that where the relator alleges specific claims in one state or region, such pleadings can satisfy Rule 9(b) requirements by establishing a nationwide inference of fraud. *Nowa*k, 806 F. Supp. 2d at 355 (citing *Duxbury,* 579 F.3d at 30 ("Although [the relator] does not identify specific claims, he has alleged the submission of false claims across a large *cross-section of providers* that alleges the 'who, what, where, and when of the allegedly false or fraudulent representation.'" (emphasis added)) and *Wall v. Vista Hospice Care, Inc.,* 778 F.Supp.2d 709, 717 (N.D. Tex. 2011) ("*If combined with sufficient number of specific, verifiable cases,* an analysis extrapolating to other patients is not fatal to [a relator's] complaint, but rather tends to strengthen the inference of fraud.")). According to the court in *Nowak*, these exceptions are particularly applicable in the off-label promotion context (not at issue here). *Nowa*k, 806 F. Supp. 2d at 355.

However, as noted by the court in *Nowak*, "even in cases employing this extrapolation approach, the successful relators have identified a nucleus of specific, allegedly fraudulent or false claims, or 'specific, verifiable cases.'" *Id.* (quoting *Wall,* 778 F.Supp.2d at 717). For example, in *Franklin,* allegations of off-label promotion and kickbacks were found to comply with Rule 9(b) because they (1) identified the individuals who trained medical liaisons to promote off-label, the medical liaisons who promoted off-label, and the physicians targeted; (2) alleged the off-label promotion "resulted in the submission of numerous . . . prescriptions that were ineligible for reimbursement under Medicaid because they were prescribed for an off-label use;" (3) were confined to a specific time period; and (4) described a marketing scheme that used kickbacks and misleading marketing to increase off-label use. *Nowak*, 806 F. Supp. 2d at 355 (citing *Franklin*, 147 F. Supp. 2d at 48).

"By contrast, in those cases in which the relator alleged no representative sample of false claims, courts have found that the relator did not satisfy Rule 9(b), regardless of the persuasiveness of the showing of the unlawful fraudulent scheme or conduct." *Nowa*k, 806 F. Supp. 2d at 356 (citing *Rost,* 507 F.3d at 733 (finding pleading insufficient where it "raise[d] facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility"); *Wall,* 778 F. Supp. 2d at 715–18 (finding a statistical inference that Medicaid and Medicare participate in as much as ninety-three percent of related cases insufficient under Rule 9(b) because there was otherwise no "verifiable cases" identifying an alleged false claim)). The *Nowak* court observed that even in *Duxbury,* which the First Circuit deemed a "close call," the relator "identified, as to each of the medical providers (the who), the illegal

kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." *Nowa*k, 806 F. Supp. 2d at 356 (quoting *Duxbury*, 579 F.3d at 30).

Relators argue the FAC contains allegations that constitute reliable indicia that support the inference that the three schemes resulted in the filing of false claims and specifically rely on the following allegations:

- Bayer and Amgen Support Services are widely used by Prescribers who prescribe Betaseron or Nexavar. **CI-3, a Betaseron drug rep, estimated that 95% of the Prescribers who prescribed Betaseron utilized Lash's Support Services. CI-6, a Nexavar drug rep, estimated that 70% of the Prescribers who prescribed Nexavar utilized the Support Services.** (FAC, ¶ 164); *see also* ¶¶ 104, 106

- The FAC alleges through statements from Beta Nurses CI-1 and CI-2 that the White Coat Marketing Program targeted high-volume Prescribers. (FAC, ¶¶ 123-24)

- The number of Medicare claims submitted for several Bayer and Amgen products, as well as Medicaid claims from numerous states. (FAC, ¶¶ 191-204).

(Docket Entry # 52 at pgs. 28-29) (emphasis added). Relators further assert the testimony of the confidential interviewees reveals the schemes had the effect of increasing prescriptions of Defendants' drugs. *Id*. ¶¶ 16-17, 99, 105, 118, 142, 165, 176. According to Relators, these allegations, taken as true, establish Defendants' Free Nurse, White Coat Marketing, and Support Services programs had the effect of inducing physicians to prescribe Bayer and Amgen products, and that at least some of those prescriptions were submitted to Medicaid and Medicare for reimbursement. (Docket Entry # 52 at pg. 30).

Unlike the relator in *Duxbury*, Relators have not sufficiently identified the who, the what, the rough time periods and locations (the where and when), and the filing of the false claims themselves. Like the relators in *Foster* and *Rost*, Relators have not provided factual details from which the Court

can reasonably infer a link between the kickback schemes and the submission of a claim for payment to the Government. *See Foster*, 587 F. Supp. 2d at 824-25 (citing *Rost*, 507 F.3d at733).

The cases relied upon by Relators, where courts have found the relators had sufficiently alleged a causal link between fraudulent conduct and the submission of false claims, involve allegations or facts more detailed than those in the FAC.[16] For example, in *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), *cert. denied sub nom. Med. Device Bus. Servs., Inc. v. U.S. ex rel. Nargol*, 138 S. Ct. 1551 (2018), relied upon by Relators in their surreply, the district court found the relators failed to identify even a single representative false claim for payment for a defective device, and the complaint did not cite sufficient "other factual and statistical evidence to strengthen the inference of fraud beyond a mere possibility." *Id*. at 33. On appeal, the First Circuit found under the "more flexible" approach to evaluating the sufficiency of fraud pleadings in connection with indirect false claims for government payment, the relators alleged causation. *Id*. at 41. However, the complaint in *Nargol* contained a description of one actual sale of a defectively manufactured product to a provider that sought government reimbursement. *Id*. at

[16] *See United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *6-10 (N.D. Tex. Sept. 30, 2016) (complaint identified specific individuals connected to the fraud, referred to specific conversations regarding false coding, and detailed the numeric value obtained by defendant in connection with each instance of fraudulent conduct); *United States ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *5 (E.D. Pa. June 3, 2015) (alleged fraudulent conduct was specifically aimed at getting reimbursements "from government programs" and relator provided specific profit figures generated by such conduct); *United States ex rel. Tucker v. Christus Health*, No. CIV.A. 09-1819, 2012 WL 5351212, at *4 (S.D. Tex. Oct. 23, 2012) (the complaint "identifie[d] by name individuals who participated in submitting the false claims to Medicare . . . specifie[d] the time period during which the false claims were submitted to Medicare . . . provide[d] specific examples of each category of fraudulent billing, and explain[ed] that Defendants received millions of dollars thereby."); *United States ex rel. DeKort v. Integrated Coast Guard Sy*s., 705 F. Supp. 2d 519, 539, 545 (N.D. Tex. 2010) (relators provided "copious detail" including several of the actual alleged false claims, such as Certificates of Compliance).

37. The complaint also alleged the sale and use of thousands of the devices, "making it virtually certain that the insurance provider in many cases was Medicare, Medicaid, or another government program." *Id*. at 41. For example, the complaint alleged approximately 18,750 devices were sold to Medicare patients alone between 2005 and 2009, and that those patients made up roughly half of the total number of people who received the devices during that timeframe. *Id*. at n. 7.

Because the relators alleged that, "over a five-year period, several thousand Medicare and Medicaid recipients received what their doctors understood to be Pinnacle MoM device implants; that more than half of those implants fell outside the specifications approved by the FDA; and that the latency of the defect was such that doctors would have had no reason not to submit claims for reimbursement for noncompliant devices," the complaint essentially alleged facts showing that it was statistically certain that DePuy caused third parties to submit many false claims to the government. *Id*. at 41. In that context, the First Circuit did not require the relators to plead false claims with more particularity than they had already done. *Id.*

Here, the facts alleged by Relators do not show it was statistically certain Defendants caused the submission of false claims to the Government, like in *Nargol*. Relators do not allege any specific instance in which one of the Covered Products was prescribed or a claim was submitted as a result of the three schemes. Relators do not make the necessary connection that any such claim was then submitted through the Medicare, Medicaid, VA, or Tricare programs to the Government. Although Relators allege that certain Prescribers were Top 1000 Medicare prescribers, they do not allege the patients with whom the confidential interviewee worked were covered by Government reimbursement programs or privately insured patients. Relators allege "nurse educators gained access

to Prescribers," (FAC ¶¶ 125-26, 128, 130), but do not sufficiently explain how this access resulted in false claims that were then submitted to the Government.

Relators rely on summaries of aggregate annual reimbursement amounts by Medicare and Medicaid for one or more of the products at issue. (FAC, ¶¶ 191-204). For example, Relators allege in 2015, approximately 40,000 Medicare Part D Claims for Betaseron were submitted, resulting in approximately $240 million in nationwide spending. *Id.* ¶ 192. According to the FACE, over $10 million was spent in each of 8 states, and the top 3 states in terms of spending were Florida ($16.2 million), California ($16 million), and Michigan ($15.6 million). *Id.* A further breakdown of each state's 2015 Medicare claim data for Betaseron was then summarized in a table. *Id.*

The charts generally show Medicare and Medicaid reimbursement for the Covered Products in 2015 (the only year Medicare figures are included) and in some cases, from 2012 to 2014 (during which some Medicaid data is included). As urged by Defendants, the charts of publicly available information regarding Medicare and Medicaid reimbursements do not remedy the disconnect between the alleged underlying conduct and any actual false claims for reimbursement. The charts show collective government reimbursement figures without any indication those statewide payments had anything to do with any alleged kickback from Defendants.

In sum, the FAC lacks the level of detail required, even under a "reliable indicia" standard, for pleading the submission of false claims. Although the FAC may raise facts that "suggest fraud was possible, it contains no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Rost*, 507 F.3d at 733. For this separate reason, the Court recommends Relators' Counts 1 and 2 be dismissed without prejudice.

Relators have only amended once, before the filing of Defendants' motion to dismiss. Considering this is the first time Relators have had the benefit of the Court's analysis of the sufficiency of their pleading, and further considering the Court has recommended Jaime Green be dismissed as a co-relator, the Court recommends Relator Health Choice Group be given leave to reassert its claims to properly allege specific conduct by each defendant, as well as to plead with more specificity as required by Rule 9(b). *See United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 785 (S.D. Tex. 2010).

IX. RULE 9(b) MOTION TO DISMISS COUNT 3

A. Defendants' assertions

In Count 3, Relators allege Defendants conspired to violate the FCA, 31 U.S.C. § 3729(a)(1)(C). FAC, ¶¶ 216-20. Specifically, Relators allege "Bayer and Amgen conspired with Amerisource and Lash, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for Covered Products dispensed in connection with the kickback scheme." *Id.* ¶ 218. Defendants assert the conspiracy claim (Count 3) should be dismissed because the FAC fails to allege the essential elements of a conspiracy claim.

B. Applicable law

To demonstrate an FCA conspiracy between Defendants, Relators must be able to show (1) the existence of an unlawful agreement between Defendants to get a false or fraudulent claim allowed or paid by a government payor and (2) at least one act performed in furtherance of that

agreement. *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343 (5th Cir. 2008). "As part of that showing, the plaintiff must demonstrate that the defendants shared a specific intent to defraud the government." *Ramsey-Ledesma*, 2016 WL 5661644, at *11. As to the first requirement, the relators are not required to demonstrate the manner in which the agreement came into being, only that an agreement did, in fact, exist. *Ruscher*, 2014 WL 2618158, at *26.

"The particularity requirements of Rule 9(b) apply to the [FCA's] conspiracy provision with equal force as to its 'presentment' and 'record' provisions." *United States ex rel. Hartwig v. Medtronic, Inc*., No. 3:11CV413-CWR-LRA, 2014 WL 1324339, at *5 (S.D. Miss. Mar. 31, 2014) (quoting *Grubbs*, 565 F.3d at 193). Therefore, in order to sustain a claim for conspiracy to commit fraud, the relator must "plead with particularity the conspiracy as well as the overt acts . . . taken in furtherance of the conspiracy." *Id.* (citation omitted).

C. Whether the FAC adequately pleads Relators' conspiracy claims

According to Relators, "each element may be inferred from circumstantial evidence," and the illegal agreement may even be "silent and informal." *United States v. Gibson*, 875 F.3d 179, 186 (5th Cir. 2017). Relators assert their allegations, when taken as true, "allow a reasonable inference that Defendants agreed, either explicitly or implicitly, to work together to enact a kickback scheme that would result in the filing of millions of dollars of false claims, thereby defrauding the government in exchange for their own profit." (Docket Entry # 52 at pg. 35).

First, Relators argue "all defendants were aware of the AKS and disregarded the fact that the alleged schemes violated the AKS (¶ 16)." *Id*. at pg. 34. However, paragraph 16 does not reveal

Defendants' supposed awareness about any AKS violations.[17] Second, Relators argue "each of the defendants had a critical role, described in detail, in the alleged schemes (¶¶ 46, 88-91, 94-99, 107-115, 140-150, 160)." As noted by Defendants, rather than describing each defendant's "critical role" or doing so "in detail," many of the allegations Relators reference are couched in terms of generalities using such prefaces as, "[i]n general," "[g]enerally," "[i]n sum," and "[p]ut simply." *Id*. (referencing FAC, ¶¶ 46, 96, 107, 145, and 150). Similarly, without offering specifics, Relators reference allegations that certain defendants engaged in general business activities "with [substantial] assistance from" Amerisource and Lash. *Id*. (referencing FAC, ¶¶ 88, 89, 91, 108, and 146).

Finally, Relators argue they have sufficiently alleged the "express purpose of the cooperation among Defendants was to hide violations of the AKS." (Docket Entry # 52 at pgs. 34-35). Relators direct the Court to ¶¶ 4-6 (alleging Bayer and Amgen, with assistance from Lash and/or Amerisource provided in-kind remuneration to Prescribers in the form of free nurse and reimbursement support services and Bayer and Amgen "contracted with and paid remuneration to Amerisource, Lash, and Ashfield" to deploy nurse educators in part to recommend the Covered Products). Relators also refer to ¶¶ 14, 108-116, asserting these allegations describe Amerisource, Lash, and nonparty Ashfield's role in hiding Bayer and Amgen's illegal remuneration and promotion schemes.

Paragraph 14 alleges:

> Although Bayer and Amgen, as well as their co-defendants, knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote the Covered Products, Defendants disregarded the law,

[17] The paragraph alleges as follows: "As is demonstrated below, due to Defendants' conduct, tens of thousands of prescriptions for the Covered Products were not based purely on clinical efficacy or patient-specific information, but rather were tainted by the unlawful, substantial kickbacks Bayer and Amgen offered Prescribers." (FAC, ¶ 16).

> choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace.

(FAC, ¶ 14). Relators further allege as follows:

- "Bayer and Amgen's relationship with Amerisource, Lash, and Ashfield plainly involves the payment of kickbacks – cash consideration – in return for services that led to prescriptions being filled and paid for with Government money." (*id.* ¶ 110);

- "Bayer and Amgen paid Amerisource, Lash, and Ashfield to hire nurse educators to recommend the Covered Products to Prescribers and patients and drive sales." (*id.* ¶ 113);

- "Bayer, Amgen, Amerisource, Lash, and Ashfield needed a clever approach to disguise this marketing strategy . . . . Since the nurses involved in this scheme were not Bayer or Amgen employees, Bayer, Amgen, Amerisource, Lash, and Ashfield could not openly pay the nurses to exclusively recommend the Covered Products." (*id.* ¶ 114);

- "In an attempt to circumvent the law, Bayer and Amgen contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to appear to be independent. Bayer, Amgen, Amerisource, Lash, and Ashfield designated the nurses as 'educators' who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to Prescribers." (*id.* ¶ 115); and

- "Although the nurses were independent contractors and were purportedly 'educators,' they were expected to and did recommend the Covered Products. This conclusion is compelled by numerous facts HCG uncovered during its investigation." (*id.* ¶ 116).

These paragraphs consist of general allegations and do not set forth any "meeting of the minds" among Defendants as required by law. *See United States ex. rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 857 (S.D. Tex. 2003). This is illustrated by the following cases.

In *United States ex rel. Boise v. Cephalon, Inc*., No. 08-287, 2015 WL 1724572, at *14 (E.D. Penn. April 15, 2015), the court held the relators' allegations gave rise to a plausible claim for conspiracy. "There the complaint alleged the existence of a specific formal agreement pursuant to which Takeda Pharmaceuticals and Cephalon allegedly conspired to promote Provigil and Nuvigil off-label, which permitted [the court] to infer allegations of agreement to support relators' conspiracy claim from relators' other factual allegations." *United States ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *13 (E.D. Pa. June 3, 2015) (citing *Boise*, 2015 WL 1724572, at *14). In *Cestra*, there "appear[ed] to be no reference to formal agreements . . . that might allow [the court] to similarly infer allegations of conspiratorial agreement from relator's conclusory statement of his conspiracy claim." *Cestra*, 2015 WL 3498761, at *13.

In *United States ex rel. McLain v. Fluor Enterprises, Inc*., No. CIV.A. 06-11229, 2013 WL 3899889 (E.D. La. July 29, 2013), the court dismissed the conspiracy claims, even though the plaintiffs had "provided the names of the parties they allege entered into a conspiracy, the alleged scheme of the conspiracy, the claims for payment constituting the alleged overt acts, as well as a window of time during which the alleged conspiracy occurred." *Id*. at *10 "What the plaintiffs ha[d] not provided [was] any indication that any of the parties actually agreed to enter into the alleged conspiracy." *Id.* According to the court, the plaintiffs' allegations were similar to the allegations against the hospital and other doctors in *Grubbs*—"they point to little more than the possibility of an agreement among the stated parties, which the *Grubbs* court held to be inadequate for the purpose of pleading a conspiracy." *Id.* (citing *Grubbs*, 565 F.3d at 193-94).

In *Ramsey-Ledesma*, Chief Judge Lynn of the Northern District of Texas held the complaint pleaded with sufficient particularity that Censeo and Altegra conspired to violate the FCA, but it

failed to plead sufficient facts to state a claim for conspiracy under the FCA as to Humana and Tufts. 2016 WL 5661644, at *12. Regarding the first two defendants, the relator had alleged "Censeo and Altegra had an agreement to generate improper and unsupported high-risk diagnosis codes for inclusion in risk adjustment data reported to CMS on behalf of Censeo's MA clients, and that both entities coded unsupported diagnoses and undiagnosed conditions." *Id.* However, the relator only generally alleged "Humana and Tufts hired Censeo to generate risk adjustment data, and that Censeo and Altegra coded unsupported medical diagnoses and undiagnosed conditions from the assessment forms completed by Censeo's physicians." *Id*.

The relator alleged Censeo and Altegra submitted inaccurate risk adjustment data based on the unsupported medical diagnoses and undiagnosed conditions "with the knowledge and consent of, and under the direction and supervision of, both Humana and Tufts," but failed to plead "any specific facts that would support the inference that Humana or Tufts had an actual agreement with Censeo or Altegra to create false records or present false claims to CMS." *Id*. The complaint did not identify any particular person who entered into an agreement on behalf of Humana or Tufts; nor did it allege "particular circumstances that would suggest a meeting of the minds." *Id*. According to the court, the relator's "reliance on her allegations regarding the existence of an alleged scheme d[id] not demonstrate that Humana or Tufts had an agreement to participate in the alleged scheme, and d[id] not satisfy the Rule 9(b) standard." *Id.*

In this case, Relators have not set forth facts alleging an agreement to conspire. There is not a factual basis to determine the roles of each defendant in any agreement or each defendant's specific intent to defraud. The Court recommends Relators' count 3 conspiracy claims be dismissed without

prejudice.[18] Relators may replead their count 3 claims that the defendant entities conspired with each other, in accordance with the direction given on page 115 herein.

X. RELATORS' STATE-ANALOGOUS CLAIMS (COUNTS 4-34)

Relators' claims for violations of the thirty-one Plaintiff States' False Claims Act statutes are asserted in Counts 4-34.[19] (FAC, ¶¶ 221-375). State law analogues to the FCA create liability for

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[18] The Court further notes Relators' conspiracy claims fail on the independent ground that Relators cannot plead a conspiracy to commit an FCA violation without successfully alleging an FCA violation. *United States ex rel. Westbrook v. Navistar, Inc.*, No. 3:10-CV-1578-O, 2012 WL 10649207, at *9 (N.D. Tex. July 11, 2012), *aff'd sub nom. United States ex rel. Spicer v. Westbrook*, 751 F.3d 354 (5th Cir. 2014) (citing *United States ex rel. Coppock v. Northrup Grumman Corp.*, No. Civ.A. 3:98–CV2143, 2003 WL 21730668, at *14 n. 17 (N.D. Tex. July 22, 2003) (Fitzwater, J.)). "[S]econdary liability for conspiracy under § 3729(a)(3) cannot exist without a viable underlying claim." *Id.* Here, the Court has found Relators' claims against Defendants for violating § 3729(a)(1) and § 3729(a)(1)(B) have not been sufficiently pleaded under Rule 9(b).

[19] The state statues are the: (1) Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 911 (as amended by 2017 Arkansas Laws Act 978 (S.B. 564)); (2) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (3) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (4) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (5) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (6) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (7) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (8) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (9) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 –31; (10) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (11) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (12) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (13) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (14) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (15) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (16) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (17) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (18) Montana False Claims Act, Mont. Code. Ann. §§ 17-8-401 – 416; (19) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (20) New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b –61-e; (21) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (22) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (23) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (24) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (25) North Carolina False Claims Act, N.C. Gen. Stat.

false claims, often with language identical or very similar to the FCA. *See id*. ¶ 40 ("Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS."). Absent allegations about how a state law differs from the FCA – which Relators have not pled here – courts interpret state false claims laws consistently with the FCA. *See, e.g. Colquitt*, 864 F. Supp. 2d at 537-38 (dismissing both FCA and state law claims with prejudice concurrently when requirements of FCA were not met and no difference in state law was shown).

Defendants assert the state law claims should be dismissed for the same reasons as the federal FCA claims and for failure to satisfy Rule 9(b). In their response, Relators assert there are in fact meaningful distinctions between the elements required under the AKS and FCA and their state equivalents. (Docket Entry # 52 at pg. 36). As one example, Relators state the Texas Medicaid Fraud Prevention Act ("TMFPA") differs substantially from the FCA by not including or requiring the presentation of a "false claim." According to Relators, instead, the TMFPA proscribes 13 enumerated unlawful acts, which generally describe material false statements and misrepresentation affecting the Medicaid program. *Compare* 31 U.S.C. §§ 3729(a)(1)(A)-(G) *with* Tex. Hum. Res. Code §§ 36.002(1)-(13).

Relators also contest Defendants' assertion the FAC does not contain state-specific allegations. Relators assert the FAC contains "evidence from confidential informants who have

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Ann. §§ 1-605 – 618; (26) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (27) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 –1.1- 9; (28) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (29) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (30) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (31) Vermont False Claims Act, Vt. Stat.Ann. tit. 32, §§ 630 – 642; (32) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (33) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

knowledge of the perpetration of the accused schemes *throughout the United States*." (Docket Entry # 52 at pg. 36) (citing FAC, ¶ 87). The FAC also alleges Defendants deployed their fraudulent schemes "across the nation, and the Covered Products were marketed prescribed, and sold nationwide. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for each of the covered products." *Id*. ¶ 59. According to Relators, details regarding Defendants' pharmaceutical sales, which were tainted by kickbacks, are provided for all fifty states. *Id*. ¶¶ 192-204.

Like federal FCA claims, state law FCA claims are also subject to Rule 9(b). *See Williams v. WMX Technologies, Inc.*, 112 F.3d 175, 177 (5th Cir. 1997). To meet this heightened pleading standard, Relators must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings. *Wall,* 778 F.Supp.2d at 723.

Relators assert their identification of a nationwide fraudulent scheme, "with representative examples of the uniform perpetration of that scheme in numerous states, is sufficient to support Relators' state law claims." (Docket Entry # 75 at pg. 12) (citing *United States v. Exec. Health Res., Inc*., 196 F. Supp. 3d 477, 496 (E.D. Pa. 2016) and *United States ex rel. Brown v. Celgene Corp.,* 2014 WL 3605896, at *10 (C.D. Cal. July 10, 2014)). According to Relators, both courts declined to dismiss state law claims despite a lack of state-specific allegations because the complaint alleged a nationwide scheme.

"In cases in which relators have alleged enough to sustain claims under state false claims statutes, the complaints have contained more facts that could raise the inference that the defendants' conduct occurred nationwide." *United States v. Medtronic, Inc*., No. CV 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017). According to the *Medtronic* court, in *Executive Health*,

"the court held that the relator sufficiently alleged a nationwide scheme because although the relator did not plead specific facts in every state, he alleged that dozens of specific hospitals around the country were the defendant's clients and that the defendant provided specific services for over half of country's hospitals." *Id*. (citing *Exec. Health Res., Inc*., 196 F. Supp. 3d at496 and *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 177 (E.D. Pa. 2012)).[20]

In the *Medtronic* case, the court held Forney's mere allegation in the amended complaint that Medtronic engaged in "nationwide marketing" was not enough to survive dismissal of her state law claims. 2017 WL 2653568, at *5. The amended complaint did not specify any customers of Medtronic outside the state of Pennsylvania, nor did the factual allegations contained in the amended complaint mention the names of any states aside from Pennsylvania. Forney only mentioned other states when she stated causes of action under the laws of those states. *Id.* Thus, the court dismissed Forney's state law claims in the amended complaint without prejudice, allowing her to replead those claims along with the federal FCA claim the court had dismissed for failure to plead with sufficient particularity. *Id.*

The Court finds Relators have not sufficiently supported their allegations that Defendants violated the false claims laws of the states on whose behalf they purport to sue. *See Wall,* 778

[20] In *Spay*, the plaintiff attached to his complaint " a chart of claims reflecting the various false PDE information submitted by Defendants and listing the violations using various identifiers including drug name, offending pharmacy, date filled, expiration date, patient co-pay, prescriber name where available." 913 F. Supp. 2d at 176. "While many of the prescriptions originated from pharmacies located in Puerto Rico—the center of MCS's service area—others originated from CVS Caremark's mail order facilities in Florida and Illinois, as well as other pharmacies in New York and Pennsylvania." *Id.* Taking all of the well-pled allegations as true, the court found a strong inference the fefendants submitted false claims nationwide, noting "the sheer number of claims identified by Plaintiff in at least three states and Puerto Rico suggests, without need for speculation, that Defendants' reporting practices likely occurred at Defendants' other facilities throughout the country." *Id*. at 177.

F.Supp.2d at 723 (dismissing without prejudice state FCA claims for those states in which the relator "provide[d] no details of the alleged fraud" because "to plead properly, even where the allegations are stated on information and belief, a plaintiff must set forth in the complaint the facts supporting the belief"). Similarly here, the Court recommends this part of Defendants' motion be granted to the extent Relators' state law FCA claims be dismissed without prejudice and Relator Health Choice Group be allowed to replead the state law claims along with its federal FCA claim.

XI. RECOMMENDATION

Based on the foregoing, it is

RECOMMENDED that Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint (Docket Entry # 38) be **GRANTED IN PART and DENIED IN PART**. It is

RECOMMENDED Defendants' motion to dismiss Jaime Green's claims be granted and Jaime Green be dismissed as a co-relator in this action; Defendants' motion to dismiss under Rule 12(b)(6) be denied; and Defendants' motion to dismiss under Rule 9(b) be granted to the extent Relators' federal and state law FCA claims be dismissed without prejudice and Relator Health Choice Group be allowed to replead. It is further

RECOMMENDED the Court allow Relator Health Choice Group to replead its federal and state law FCA claims within twenty days following any Order Adopting this Report and Recommendation, to the extent it deems appropriate to address the deficiencies identified herein and to further order that if and when Relator Health Choice Group files a Second Amended Complaint, it shall also attach a redlined copy as an exhibit.

Objections

Within fourteen (14) days after receipt of this Amended Report and Recommendation, any party may serve and file written objections to the findings and recommendations of the magistrate judge. 28 U.S.C.A. 636(b)(1)(C).

Failure to file written objections to the proposed findings and recommendations contained in this report within fourteen days after service shall bar an aggrieved party from *de novo* review by the district court of the proposed findings and recommendations and from appellate review of factual findings accepted or adopted by the district court except on grounds of plain error or manifest injustice. *Thomas v. Arn*, 474 U.S. 140, 148 (1985); *Rodriguez v. Bowen*, 857 F.2d 275, 276-77 (5th Cir. 1988).

SIGNED this 29th day of June, 2018.

CAROLINE M. CRAVEN
UNITED STATES MAGISTRATE JUDGE